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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MSP RECOVERY CLAIMS, SERIES LLC, a Delaware series limited liability company; MSPA CLAIMS I, LLC, a Florida limited liability company; MSP Recovery Claims Series 44, LLC, a Delaware series limited liability company; MSP Recovery Claims PROV, Series LLC, a Delaware series limited liability company; and MSP Recovery Claims CAID, Series, LLC, a Delaware series limited liability company; on behalf of themselves and all others similarly situated

Plaintiffs,

v.

ACTELION PHARACEUTICALS US, INC., a Delaware corporation; CARING VOICE COALITION, INC. an Idaho non-profit corporation; and ADIRA FOUNDATION, a Virginia non-profit corporation,

Defendant(s).

Case No.: 3:22-cv-07604

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

Plaintiffs, MSP Recovery Claims, Series LLC ("MSPRC"); MSPA Claims 1, LLC ("MSPA"); MSP Recovery Claims Series 44, LLC ("Series 44"); MSP Recovery Claims PROV, Series LLC ("Claims PROV"); MSP Recovery Claims CAID, Series LLC ("Claims CAID") (hereinafter all plaintiffs collectively referred to as, "Plaintiffs"), on behalf of themselves and other Medicare Advantage health plans[1] and Medicaid health plans[2] (collectively, "Class Members"),[3] sue Actelion Pharmaceuticals US, Inc. ("Actelion"), Caring Voice Coalition, Inc. ("CVC") and Adira Foundation f/k/a Facilitating Patient Health ("Adira") (hereinafter all defendants collectively referred to as "Defendants"), allege:

NATURE OF ACTION

1. This case arises out of Actelion's conspiratorial schemes to increase the unit price and quantity dispensed of Tracleer, Opsumit, Veletri, and Ventavis ("Subject Drugs" or "Actelion Drugs") which is used to treat pulmonary arterial hypertension ("PAH"). As a result of these schemes, Plaintiffs' Assignors ("Assignors") and the Class Members paid supra-competitive prices for Actelion Drugs and for artificially inflated quantities of dispensed Actelion Drugs on behalf of beneficiaries enrolled in their health plans ("Enrollees").

2. RICO Defendants created a scheme to circumvent Congressionally mandated co-payment requirements (referred to as "Co-Payment Scheme" or "Scheme") designed to reduce sensitivity to the ever-increasing drug prices and increased dispensing of Actelion Drugs.[4]

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[1] "Medicare Advantage health plans" is defined as Medicare Advantage entities such as Medicare Advantage organizations ("MAOs"), Independent Practice Associations ("IPAs"), Management Service organizations ("MSOs"), Health Maintenance organizations ("HMOs"), Part D Sponsors, and other Medicare first tier, downstream, and related entities. Throughout the Complaint, "MA Plan" is used as a shorthand for all such Medicare Advantage health plan entities.

[2] "Medicaid health plans" is defined to include Medicaid Managed Care Organizations ("MCO") and other Medicaid first tier, downstream, and related entities. Throughout the Complaint, "Medicaid Plans" is used as a shorthand for all such Medicaid health plan entities.

[3] The full class is defined *infra*, Section V.

[4] When Medicare beneficiaries, including those covered by Medicare Advantage health plans, obtain a prescription drug, the beneficiaries need to make a co-payment. Congress included co-payment requirements in the Medicare structure, in part, to encourage market forces to serve as a check on health care costs, specifically including the prices that pharmaceutical companies can demand for their drugs. Austin Frerick, A., *The Cloak of Social Responsibility: Pharmaceutical*

3. Defendants executed their Scheme, engaging in numerous overt acts that both effectively eliminated price sensitivity, allowing Actelion to raise their prices to supra-competitive levels, without concern of their product not being dispensed due to patient financial restrictions which caused the over-dispensing of supra-competitively priced drugs. This resulted in cognizable economic damages as Assignors and Class Members lost money or property they otherwise would still have but-for the Co-Payment Scheme.

4. Actelion and CVC colluded and agreed that CVC would act as an illegal conduit, disguised as an independent charity, by which Actelion could funnel kickbacks to pharmacies through CVC's disease funds. Actelion and CVC agreed that CVC would create a PAH Fund that would exclusively, or nearly so, cater to patients taking the Subject Actelion Drugs and that Actelion would be the sole donor to CVC's PAH Fund.

5. Actelion bribed CVC to serve as Actelion's conduit and funnel kickbacks to pharmacies.

6. As part of this Scheme, Actelion routinely obtained data from CVC detailing how many patients taking each Subject Drug CVC had assisted, how much CVC had spent on those patients, and how much CVC expected to spend on those patients in the future. This information was used to ensure that CVC used the purported "donations" for Actelion Drugs only, and allowed Actelion to perform return on investment calculations.

7. Actelion and CVC routinely exchanged information to ensure Actelion possessed sufficient data to maximize profits from its "donations" to CVC.

8. Defendants also funneled MA Plan and Medicaid Plan patients away from Actelion's free drug program. Defendants excluded individuals from participating in Actelion's free drug program because the individuals were eligible for participation in the federal health programs. In other words, Defendants treated customers differently based on eligibility for participation in the federal health programs.

Corporate Charity, TAX NOTES, Vol. 153, No. 9, Nov. 28, 2016. [hereinafter *Cloak of Social Responsibility*].

9. Actelion's bribes to CVC and Defendants' illegal renumerations to federal healthcare program beneficiaries constituted violations of the federal Anti-Kickback Statute ("AKS"), thereby rendering each claim unpayable by federal healthcare programs and disqualifying Actelion from receiving any payment from such programs for the Subject Drugs during the course of the Scheme.

10. Actelion ensured that the large sums of money continuously paid to CVC improperly influenced CVC's practices. Likewise, Defendants ensured that the co-payment assistance grants—paid for and facilitated by Actelion, and distributed by CVC—improperly influenced patients receiving and/or pharmacies dispensing Actelion Drugs.

11. In doing so, Defendants eliminated the effects of price sensitivity—because the patients (i.e., consumers) were no longer incurring any cost—thereby elimination price considerations, thus artificially increasing the quantity dispensed by pharmacies, and the amount of claims paid by Assignors and Class Members for Actelion Drugs. Accordingly, with price sensitivity eliminated, the Co-Payment Scheme allowed Actelion to circumvent congressional safeguards and artificially increase the price of Actelion Drugs for all prescriptions to supra-competitive levels.

12. As a result, the Assignors and Class Members were forced to pay artificially increased prices for Actelion Drugs prescriptions and for an increased quantity of claims for Actelion Drugs. This resulted in cognizable economic damages as the Assignors and Class Members paid substantially more than they otherwise would have—but for the Co-Payment Scheme.

13. Actelion, a sophisticated pharmaceutical manufacturer, knew that the intended victims of the Scheme were the health plans Plaintiffs seek to represent. Indeed, after a patient's cost sharing obligation is paid, health plans such as the Assignors and Class Members must then pay for Actelion Drugs. To be clear, if a patient does not provide their cost sharing obligations (e.g., co-pay), a prescription will not be dispensed from a pharmacy.

14. On December 5, 2018, Actelion paid $360 million to settle the United States' claims that Actelion violated the AKS and False Claims Act ("FCA"). Actelion entered into a Settlement Agreement with the United States of America ("Actelion Settlement"), with the United States

Department of Justice ("DOJ") and on behalf of the Office of Inspector General ("OIG") of the Department of Health and Human Services related to the general conduct at issue in this lawsuit. *See* Actelion Settlement Agreement, attached as **Exhibit A**; *See also* DOJ Settlement Agreement Press Release, attached as **Exhibit B**.

15. The Actelion Settlement did not address or settle damages sustained by the Assignors and Class Members. The terms of the Actelion Settlement did not address the claims Plaintiffs set forth in the action.

16. Additionally, CVC made several fraudulent and voidable transfers to Adira, in violation of Va. Code Ann. §§ 55.1-400 *et seq*.

17. Adira is the de facto successor of CVC. Adira was created by and has always been operated by the very same people who operated CVC—including, but not limited to Greg Smiley, James Rock, and Bruce Packett. Adira received the remainder of CVC's assets, including cash, investments, and valuable personal property. Adira received and continues to maintain all of CVC's data including taking ownership and control of what CVC described as its "home-grown patient portal for monitoring patient and grant data—known in shorthand by previous leadership as PAMS [which] was [CVC's] largest and most significant of assets." As CVC's successor, Adira is liable for CVC's debts and liabilities.

18. Additionally, and upon information and belief, after CVC allegedly ceased operations, CVC and Adira contacted Actelion and agreed to transfer millions of dollars of illicit funds to Adira, where both Adira and Actelion continued taking overt acts in furtherance of their scheme to defraud third-party payors. As a coconspirator to the scheme to defraud, Adira is jointly and severally liable for the harm caused by CVC's and Actelion's conduct.

19. Indeed, each Defendant is jointly and severally liable for the conduct of the others.

20. Plaintiffs bring this lawsuit to redress the damages sustained by Assignors and Class Members as a result of Defendants' unlawful Scheme to increase the prices and dispensed quantities of Actelion Drugs.

21. The improper actions alleged here have allowed Actelion to maintain supra-competitive prices by eliminating price sensitivity that would have directly benefited consumers and

the public at large. Price sensitivity counterbalances Actelion's desire to inflate prices for medically necessary drugs–which is why Congress relies on price sensitivity as a vital mechanism for combating supra-competitive pricing for Government payors. CVC's co-payment assistance program allowed Actelion to increase the price of the Actelion Drugs regardless of the relevant market conditions by insulating Actelion from the realities of patients' inability to afford high co-payment obligations—obligations that would have had to have been capped at a reasonable amount but-for the unlawful Scheme alleged herein. Not only did this allow Actelion to charge supra-competitive prices, but also resulted in the artificially increased volume of dispensed Actelion Drugs.

22. Defendants used mail and wires in furtherance of their racketeering Scheme. Actelion used the wires to transmit their "donations" to CVC, which, in reality, were bribes to CVC. CVC would then transmit data using the mail and wires, allowing Actelion to perform what amounted to return on investments ("ROI") calculations on their "donations." Defendants would also use the mail and wire to communicate with pharmacies regarding, among other things, co-payments for patients prescribed Actelion Drugs. This resulted in the further use of mail and wires by pharmacies submitting claims for payment to Plaintiffs and Assignors.

23. RICO Defendants' conduct violated the AKS, 42 U.S.C. § 1320a-7b, the Travel Act, 18 U.S.C. § 1952 ("Travel Act"), Mail Fraud, 18 U.S.C. § 1341, and Wire Fraud, 18 U.S.C. § 1343.

I. PARTIES, JURISDICTION, AND VENUE

Plaintiffs

24. Plaintiffs are companies that obtained assignments from their Assignors to recover reimbursement or payment from Defendants. The Assignors provide health insurance coverage, pursuant to Medicare Part C and Part D and Medicaid on behalf of their Enrollees. Specifically, the Assignors made payments on behalf of, or otherwise became financially responsible for the cost of the illegally inflated and excessively dispensed Actelion Drugs as a result of the Scheme.

25. Each and every cause of action identified in this Complaint was expressly assigned to the named Plaintiffs.

MSPRC

26. MSPRC is a Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. MSPRC's limited liability company agreement provides for the establishment of one or more designated Series.

27. MSPRC has established various designated series pursuant to Delaware law to maintain various claims recovery assignments separate from other Company assets, and to account for and associate certain assets with certain particular series. Pursuant to MSPRC's limited liability agreement, all designated series form a part of MSPRC. MSPRC may receive assignments in the name of MSPRC and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, MSPRC will maintain the right to sue on behalf of each series and pursue any and all rights, benefits, and causes of action arising from assignments to a series. Any claim or suit may be brought by MSPRC in its own name, or it may elect to bring suit in the name of its designated series, under its bylaws. MSPRC's limited liability agreement provides that any rights and benefits arising from assignments to its series shall belong to MSPRC. MSPRC's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

28. Each and every cause of action identified in this Complaint was expressly assigned to MSPRC.

MSPA

29. MSPA is a limited liability company that is duly organized, validly existing, and in good standing under the laws of Florida, with its principal place of business in Coral Gables, Florida. One or more health plans irrevocably assigned to MSPA the right to assert the causes of action alleged in this Complaint. As a result of said assignments, MSPA is authorized and empowered to obtain the relief sought herein. MSPA's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

30. Each and every cause of action identified in this Complaint was expressly assigned to MSPA.

Series 44

31. Series 44 is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Series 44's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series.

32. Series 44 has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Series 44. Series 44 may receive assignments in the name of Series 44 and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Series 44 and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Series 44 retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. Series 44's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

33. Each and every cause of action identified in this Complaint was expressly assigned to Series 44.

Claims PROV

34. Claims PROV is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims PROV's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware Law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims PROV established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series.

35. Claims PROV has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims PROV. Claims PROV may receive assignments in the name of Claims PROV and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims PROV and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims PROV retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of Claims PROV the right to assert the causes of action alleged in this Complaint. As a result of said assignments, Claims PROV, through its operating agreement, is authorized and empowered to obtain the relief sought herein. Claims PROV's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

36. Each and every cause of action identified in this Complaint was expressly assigned to Claims PROV.

Claims CAID

37. Claims CAID is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims CAID's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims CAID established various designated series to serve as units of the company for the purpose of maintaining various assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series.

38. Claims CAID has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims CAID. Claims CAID may receive assignments in the name of Claims CAID and further associate

such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims CAID and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims CAID retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plan irrevocably assigned to certain series of Claims CAID the right to assert the causes of action alleged in this Complaint. As a result of said assignments, Claims CAID, through its operating agreement, is authorized and empowered to obtain the relief sought herein. Claims CAID's assignments, samples of which are alleged in detail in the Appendix to this Complaint, are valid and binding contracts.

39. Defendants' Co-Payment Scheme triggered payment obligations of the Assignors and Class Members. These actions caused the Assignors and Class Members to pay artificially inflated prices and purchase artificially inflated quantities of Actelion Drugs. This illegal conduct directly harmed Assignors and the Class Members.

40. Each and every cause of action identified in this Complaint was expressly assigned to Claims CAID.

Defendants

Actelion

41. Actelion is a Delaware corporation with principal executive offices located in South San Francisco, California. Actelion manufacturers and markets pharmaceutical products that are approved for pulmonary arterial hypertension. At all relative times, Actelion advertised, marketed, and sold pharmaceutical products, including the Subject Drugs, throughout all states and territories in the United States, including California. Actelion derived substantial revenue related to the Subject Drugs from its business throughout each of the states and territories of the United States, including California.[5]

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[5] *See,* **Exhibit 3** – Actelion 1999 Financial Reports; **Exhibit 4** – Actelion 2000 Financial Reports; **Exhibit 5** – Actelion 2001 Financial Reports; **Exhibit 6** – Actelion 2002 Financial Reports; **Exhibit 7** – Actelion 2003 Financial Reports; **Exhibit 8** – Actelion 2004 Financial Reports; **Exhibit 9** – Actelion 2005 Financial Reports; **Exhibit 10** – Actelion 2006 Financial Reports; **Exhibit 11** –

42. This Court has personal jurisdiction over Actelion because Actelion's principal executive offices are located within the state of California and therefore Actelion is at home in the state.

CVC

43. CVC is an Idaho corporation claiming 501(c)(3) status for tax purposes. CVC's principal place of business during the duration of the Scheme was located at 6606 West Broad Street, Suite 403, Richmond, Virginia 23230, however, pursuant to a filing with the Commonwealth of Virginia, on July 31, 2019, CVC, changed their principal place of business to P.O. Box 28955, Henrico, VA 23228. CVC was established in 2003 and operates disease funds, including the PAH Fund, to pay the co-payments of certain patients, including Medicare and Medicaid patients. **Exhibit 22** – CVC & Adira Business Records

44. This Court has personal jurisdiction over CVC because CVC's conduct as a member of the Co-Payment Circumvention Enterprise (defined below) constitutes "certain minimum contacts with the forum such that the maintenance of the suit does not offend traditional conceptions of fair play and substantial justice" therefore satisfying California's Long Arm Statute. *International Shoe Co. v. State of Washington*, 326 U.S. 310, (1945); Cal. Civ. Proc. Code § 410.10. CVC transacts its affairs in the State of California. CVC further engaged in the substantial and not isolated activity throughout the State of California. As a result of the Co-Payment Scheme, the Assignors and Class Members sustained financial and economic injuries in the State of California. CVC maintains systematic and continuous contacts in the State of California, and regularly transacts business in the State of California. CVC purposefully availed itself of the privilege of conducting activities in the State of California, thus benefiting from the protections and benefits of the law and conducting its affairs in the State of California. Furthermore, at all relevant times herein, CVC contracted with Actelion.

Actelion 2007 Financial Reports; **Exhibit 12** – Actelion 2008 Financial Reports; **Exhibit 13** – Actelion 2009 Financial Reports; **Exhibit 14** – Actelion 2010 Financial Reports; **Exhibit 15** – Actelion 2011 Financial Reports; **Exhibit 16** – Actelion 2012 Financial Reports; **Exhibit 17** – Actelion 2013 Financial Reports; **Exhibit 18** – Actelion 2014 Financial Reports; **Exhibit 19** – Actelion 2015 Financial Reports; **Exhibit 20** – Actelion 2016 Financial Reports; **Exhibit 21** – Actelion 2017 Financial Reports

Adira

45. Adira is a Virginia corporation claiming 501(c)(3) status for tax purposes. Adira's principal office is located at 7330 Staples Mill Road #288, Henrico, VA, 23228-4122. Adira, originally incorporated under the name Facilitating Patient Health, was established in 2019 and operates disease funds to pay the co-payments of certain patients, including Medicare and Medicaid patients. **Exhibit 22 –** CVC & Adira Business Records.

46. This Court has jurisdiction over Adira because Adira is a successor company of CVC, and as noted above, this Court has personal jurisdiction over CVC. *Successor Agency to Former Emeryville Redevelopment Agency v. Swagelok Co.*, 364 F. Supp. 3d 1061, 1074 (N.D. Cal. 2019); International Shoe Co., 326 U.S. at 316; Cal. Civ. Proc. Code § 410.10.

47. This Court has federal question jurisdiction pursuant to 28 U.S.C. § 1331. The causes of action alleged in this Complaint arise under federal law.

48. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(a), because Plaintiffs are completely diverse from Defendants and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

49. This Court has subject matter jurisdiction under 28 U.S.C. § 1332(d), because at least one member of the Class is a citizen of a state different from Defendants and the amount in controversy exceeds $5,000,000.00, exclusive of interest and costs.

50. This Court also has supplemental jurisdiction under to 28 U.S.C. § 1367, as the state law claims are so related to the federal claims as to form part of the same case or controversy.

51. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(2) because a substantial part of the events that gave rise to this lawsuit occurred in California. Venue is also proper in this district under 18 U.S.C. § 1965(a) because Defendants transact their affairs in California.

DIVISIONAL ASSIGNMENT

52. This action is properly assigned to the San Francisco/Oakland Division of this District pursuant to N.D. Cal. L.R. 3-2, because Defendant Actelion's principal place of business is in San Francisco County, which is served by the San Francisco Division. Moreover, Defendant

Actelion conducts substantial business in San Francisco County, which is served by this Division.

II. STANDING

53. The Assignors provide health care benefits to their Enrollees under either (i) contractual agreements, such as participation and network agreements with capitation and risk sharing arrangements; or (ii) state and federal laws that provide for the reimbursement of payments made by the assignor health plans.

54. The assignment agreements between Assignors and Plaintiffs are valid and binding contracts, expressly empowering Plaintiffs to bring and recover on the claims asserted in this lawsuit.

55. Plaintiffs seek recovery on behalf of each of their Assignors who paid for or reimbursed the cost of Actelion Drugs at supra-competitive prices and paid for inflated quantities of Actelion Drugs. An explanation of the representative assignment for each named Plaintiff is provided in the Appendix.

56. Plaintiffs seek recovery on behalf of each of their Assignors who paid for or reimbursed claims relating to Actelion Drugs tainted by Defendants' violations of the AKS.

57. At all material times hereto, one or more Assignor(s) provided Medicare benefits to MA Plan beneficiaries and one or more Assignor(s) provided Medicaid benefits to Medicaid Plan beneficiaries. The Assignors paid supra-competitive prices for Actelion Drugs and paid for artificially inflated dispensed quantities of Actelion Drugs as a result of Defendants' Scheme. The Assignors also paid claims for Actelion Drugs tainted by Defendants' AKS violations.

58. Defendants' Scheme triggered payment obligations for Actelion Drugs at inflated prices and induced the artificially increased dispensing of Actelion Drugs over cheaper and therapeutically equivalent generic or alternative treatments.

59. Assignors paid approximately $31 million in claims on behalf of covered patients receiving the Actelion Drugs from at least January 1, 2014, through present.

60. Assignors provided payment for Actelion Drugs throughout the United States.

III. REGULATORY BACKGROUND

61. In 1965, Congress amended the Social Security Act to create the Medicare Act under Title XVIII of the U.S. Code. The Medicare Act created a federally funded health insurance program for the nation's elderly and disabled. The Medicare Act consists of five parts—Parts A, B, C, D and E. Part A and Part B create, describe, and regulate traditional fee-for-service, government-administered Medicare. Part C outlines the Medicare Advantage program and provides that Medicare beneficiaries may elect for private insurers to deliver their Medicare benefits. Part D provides for prescription drug coverage to Medicare beneficiaries. Part E includes "Miscellaneous Provisions." Plaintiffs' Assignors provide Medicare benefits under Parts C and D.

62. Medicare Part D coverage is a voluntary prescription drug benefit program for Medicare beneficiaries established in 2003. Medicare Part D took full effect in 2006. A beneficiary may enroll in Part D if he or she lives in the service area of a Part D plan and is entitled to Medicare benefits under Part A or enrolled under Part B.

63. Unlike Parts A and B, yet much like Medicare Part C, Medicare Part D is based on a private-market model, where Medicare contracts with private entities, known as Part D "sponsors." These sponsors administer prescription drug plans, and plan sponsors must provide qualified prescription drug coverage.

64. A Part D sponsor submits a bid the year before it is to deliver Part D benefits. The bid contains a per member, per month cost estimate for providing Part D benefits to an average Medicare beneficiary in the geographic area.

65. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary may have to pay the difference as part of a monthly premium. Centers for Medicare and Medicaid Services ("CMS") then provides each Part D plan sponsor with advance monthly payments equal to the Part D plan sponsor's standardized bid. Part D plans are required to include some cost sharing obligations that the beneficiary must satisfy.

66. All providers and suppliers of medical services and items—including drug manufacturers who supply covered medications indirectly—must enroll with Medicare to be eligible to receive any payment under Medicare. 42 CFR § 424.505. To enroll in Medicare, all

providers and suppliers must submit an enrollment application to CMS and must "attests that the information submitted is accurate and that the provider or supplier is aware of, and abides by, all applicable statutes, regulations, and program instructions." 42 CFR § 424.510(d)(3).

67. The application forms used by all providers and suppliers to enroll in Medicare includes the following attestation: "I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in . . . this application. . . . I understand that payment of a claim by Medicare *is conditioned upon* the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b))."[6] (emphasis added).

68. In addition, "in order for coverage to be available under Medicare Part D for applicable drugs of a manufacturer, the manufacturer must," among other things, enter "into and have in effect an agreement described in § 423.2315(b)." 42 CFR § 423.2310(a). This manufacturer agreement requires that "[e]ach manufacturer . . . must comply with the requirements imposed by CMS . . . for purposes of administering the program." 42 CFR § 423.2315. Congress has unequivocally instructed that "compliance with federal health care laws, including the [AKS], is a condition of payment by the Medicare program." *McNutt ex rel. U.S. v. Haleyville Med. Supplies, Inc.,* 423 F.3d 1256, 1260 (11th Cir. 2005).

69. Likewise, MA Plans are required to certify compliance with the AKS and are prohibited from paying for claims that are tainted by an AKS violation or are rendered unpayable due to disqualifying conduct by the underlying provider or supplier. 42 CFR § 422.504(h)(1). Every subcontract that the MA Plan enters into must also contain this certification of compliance. 42 CFR § 422.504(i).

70. MA Plans and other Part C entities play an important role in the American healthcare landscape. They provide thousands of Americans with not only health insurance, but with the freedom to go into the marketplace and select the health insurance that best meets their needs.

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[6] Medicare Enrollment Application, CMS Form 855i, Available at: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf. *See also* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/Enrollment-Applications

Indeed, "Congress's goal in creating the Medicare Advantage program was to harness the power of private sector competition to stimulate experimentation and innovation."[7] In 2017, 33% of Medicare-eligible individuals received their health insurance from MA Plans.

71. Similarly, while Medicaid is jointly funded by state and federal governments, it is largely administered by private MCOs. When administered directly by the state, Medicaid operates as a fee-for-service plan—similar to Medicare Parts A & B. As of 2016, over two-thirds of all Medicaid beneficiaries receive their care in risk-bearing MCO plans. A co-pay assistance grant can easily influence these beneficiaries—even if their cost sharing obligation is already low—because Medicaid is specifically designed for individuals and families near or below the poverty line.

IV. FACTUAL ALLEGATIONS

72. "Part D enrollees with high drug costs can have difficulty affording their medications when they are in the deductible phase [and] when they reach the coverage gap—theperiod in which they are required to pay a larger share of total drug costs."[8] Legitimate patient assistance programs ("PAPs") aim to help financially needy patients afford necessary medications during this difficult period.

73. There are two ways that pharmaceutical companies give to PAPs. First, manufacturers can establish their own PAPs. "Under this option, pharmaceutical companies give drugs directly to patients who cannot afford them or donate the drugs to a foundation that then gives them to patients. The second option is through independent charity PAPs (herein referred to as "co-payment charities")." *See The Cloak of Social Responsibility*.

74. At all relevant times herein, CVC and Adira represented to government agencies, third-party payors, health care providers, and the public at large, that they operated legitimate independent charity PAPs, or co-payment charities.

75. Pharmaceutical companies donate money to the co-payment charities, purportedly to

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[7] *In re Avandia Mktg. Sales Practices & Prods. Liab. Litig.*, 685 F.3d 353, 363 (3rd Cir. 2012).

[8] Congressional Research Service, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*, June 15, 2017.

help patients who cannot afford their drugs. These patients often have health insurance (usually Medicare or Medicaid) but apply to these charities to help cover all, or a portion of, their co-payment obligations.

76. There are two key differences between these two giving options. "First, companies donate drugs in option 1 and money in option 2. Second, pharmaceutical companies receive no money besides a [tax] deduction in option 1, *but under option 2 they receive a [tax]* deduction and money from the insurer paying the other portion of the drug costs. Thus, assistance provided by option 2 reduces out-of-pocket costs to insured patients but do[es] not reduce the price of prescription drugs to the healthcare payer. These are one-sided discounts." *Id*. (emphasis added).

77. Small donations to a co-payment charity may substantially increase revenue received by a given pharmaceutical company from MA Plans and Medicaid Plans, such as the Assignors.[9]

78. As pharmaceutical drug company "giving" to co-payment charities rises, the co-payment charity benefits as well. In fact, executives at co-payment charities are among some of the *highest paid executives* in the United States.

79. Thus, in this context, pharmaceutical companies and co-payment charities have a mutually beneficial purpose—to receive donations, establish additional disease funds to cover co-payments of the pharmaceutical company's expensive specialty drugs, and ensure federal healthcare programs bear the cost of these drugs. Together, the co-payment charity can show "results" for the pharmaceutical company and justify increased donations.

80. Often these charities receive bribes from pharmaceutical companies to assist certain

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[9] *See* Michael Banigan, *A Guide to Patient Assistance Programs: What You Need to Know to Promote Patient Advocacy and Maximize Charitable Contributions*." Chronic Disease Fund Inc. (2016) (providing that pharmaceutical companies can calculate their profitability, or "charitable margin," as a result of their donations to co-payment charities and can stand to earn 220 percent charitable margins); *see also Cloak of Social Responsibility* (explaining that example of "charitable margin" can yield a "charitable margin of 220 percent"); Citi Research, *The Straw that Could Break the Camel's Back*: *DOJ/OIG Action on Foundation Funding Could Severely Impede Industry Returns*, May 16, 2017 [hereinafter *Citi Research*] (explaining that "[e]ach $1m industry donation to a charitable foundation to enable Medicare patients Xtandi access or similar high priced drugs has the potential to generate up to $21m for the sponsor company, ***funded by the US Government***") (emphasis added).

patients with enrolling in Medicare and Medicaid programs.

81. Given these shared economic incentives, it is no surprise that charitable assistance from co-payment charities increased from $11 million in 2004 to nearly $868 million in 2014. *See Cloak of Social Responsibility* (noting that from 2007 to 2009, during the Great Recession,

pharmaceutical giving increased by nearly $1.5 billion, while overall corporate giving decreased by $1.2 billion). The chart below details total giving for certain co-payment charities, including CVC, from 2001 to 2014.

Table A-1. Total Giving in Dollars for Independent Charity Patient Assistance Programs (PAPs), 2001-2014

	Patient Access Network Foundation[a]	Chronic Disease Fund/ Good Days[b]	Caring Voice Coalition[c]	Healthwell Foundation[d]	Patient Services	Subtotal: Independent Charity PAPs
2001	—	—	—	—	$2,328,611	$2,328,611
2002	—	—	—	—	$3,296,181	$3,296,181
2003	—	—	—	—	$5,118,345	$5,118,345
2004	—	—	$80,383	—	$6,932,842	$11,301,748
2005	$7,557,312	$5,597,689	$5,257,803	$15,856,793	$15,719,269	$49,988,866
2006	$18,652,834	$66,279,917	$9,850,206	$47,289,619	$15,333,700	$157,406,276
2007	$24,880,629	$63,551,700	$15,816,549	$59,391,157	$21,467,030	$185,107,065
2008	$32,825,596	$82,133,885	$27,943,050	$57,521,456	$35,269,942	$235,693,929
2009	$37,323,252	$136,713,152	$37,530,583	$71,425,660	$29,594,995	$312,587,592
2010	$37,562,665	$172,488,043	$38,166,963	$84,233,714	$37,440,434	$369,891,819
2011	$28,379,485	$196,647,202	$46,827,156	$49,521,777	$39,983,874	$360,359,494
2012	$108,460,641	$182,365,638	$58,221,721	$36,995,288	$50,332,148	$436,375,436
2013	$174,340,174	$194,448,004	$67,435,466	$31,135,498	$60,897,475	$528,256,617
2014	$496,427,781	$170,628,208	$98,027,589	$29,089,150	$73,735,080	$867,857,753

Source: ProPublica's Nonprofit Explorer Database.
Notes: These totals come from line 13 titled "Total Grants" on Form 990, although for some entities before 2008, the totals come from line 23, part II.
[a]Excluded 2004 return because it was an initial return.
[b]Excluded 2004 return because it was an initial return.
[c]Excluded 2002 return because it was an initial return and their reporting years run July to June.
[d]Excluded 2004 return because it was an initial return.

82. The rise of co-payment charities and pharmaceutical corporate giving to such charities (with the economic incentives detailed above) is tied to the enactment of public insurance programs expanding the number of Americans with prescription drug coverage, the growth of specialty drugs, and the federal anti-kickback law.

83. First, this increased giving to co-payment charities occurred during a period in which there was a surge in the number of Americans with prescription drug coverage as a result of the enactment of Medicare Part D and, subsequently, the passing of the Affordable Care Act in 2010 ("ACA"), which expanded prescription drug benefits. "Before these public insurance expansions,

federal government spending on prescription drugs was 25 percent of total spending in 2005. In 2014 it was 41 percent." *See Cloak of Social Responsibility*.

84. Specialty drug prices are set by drug manufacturers with an intimate knowledge of the drug market. This knowledge enables manufacturers to set supra-competitive drug prices by using PAPs to circumvent beneficiary co-payment obligations, thus eliminating price sensitivity.

85. Second, along with these public insurance programs, specialty drugs (i.e., generally defined as expensive prescriptions requiring extra handling or administration in treating complex diseases) have contributed to the growth of co-payment charities. "In recent years, spending for specialty drugs has grown faster than spending for other pharmaceuticals. Although specialty medications account for only one percent of prescriptions, they account for almost a third of U.S. prescription spending. For Medicare Part D, specialty drugs accounted for a quarter of a percent of prescriptions in 2013 but eleven percent of total drug cost." *Id*.

86. Co-payment charities allow pharmaceutical companies to manage price sensitivity for these more expensive specialty drugs. The OIG noted that PAPs "may steer patients toward and lock them into a particular manufacturer's product, even when other equally effective and less costly alternatives are available." *Id*.

87. Moreover, the rise of co-payment charities stemmed from federal anti-kickback law. The AKS made the receipt of kickbacks, bribes, or rebates in connection with items or services covered by the Medicare and Medicaid programs a crime. The AKS makes it a crime to knowingly and willfully offer, pay, solicit, or receive any renumeration to induce a person to purchase or recommend any good, service, or item covered under a federal health care program. *See* 42 U.S.C. § 1320a-7b(b).

88. As it relates to PAPs, the OIG has stated that the AKS could be violated "if a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor's federally reimbursable items," as well as if a PAP's grant of financial assistance to a patient is made "to influence the patient to purchase (or induce the patient's physician to prescribe) certain items." *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31120, 31121 (May 30, 2014), attached as **Exhibit 24**.

89. Congress has determined that any Medicare or Medicaid claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim" for purposes of the FCA. *See* 42 U.S.C. § 1320a-7b(g).

A. OIG Guidance for Co-Payment Charities

90. The OIG has provided guidance to co-payment charities regarding compliance with applicable laws and regulations, including the AKS and FCA. In this guidance, the OIG made clear that such charities will violate those laws and regulations if they do not follow specified rules. Those rules ensure that a pharmaceutical manufacturer cannot control a co-payment charity, or receive information from such a charity, that would allow the manufacturer to link the amount it donates to additional profits from the sale of a particular drug.

91. In 2005, the OIG issued a special advisory bulletin on PAPs ("2005 Bulletin"). The 2005 Bulletin provided that certain cost-sharing subsidies provided by bona fide, independent PAPs unaffiliated with drug manufacturers do not raise AKS concerns, even if the PAPs receive manufacturer contributions. *See OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623 (Nov. 22, 2005), attached as **Exhibit 25**. The 2005 Bulletin also set forth factors that the OIG considers to be "fundamental" to a properly structured, independent, bona fide PAP, including the following:

a. No drug manufacturer or donor exerts any direct or indirect influence or control over the PAP;

b. The PAP awards assistance in a truly independent manner that severs any link between the drug manufacturer donors funding and the beneficiary;

c. The PAP awards assistance without regard to the drug manufacturer's interests, or the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan;

d. The PAP provides assistance based upon a reasonable verifiable, and uniform measure of financial need applied in a consistent manner; and

e. the drug manufacturer does not solicit or receive data from the PAP that would allow the manufacturer to substantiate the amount of its donations with the number of subsidized prescriptions for its products. *Id.* at 70626-27 ("Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries drug choices.")

92. In 2014, the OIG issued an updated bulletin raising concerns about the conduct of co-payment charities and intensifying its scrutiny of arrangements between pharmaceutical companies and co-payment charities ("2014 Bulletin"). *See Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31120 (May 30, 2014), attached as **Exhibit 24**. In the 2014 Bulletin, the OIG stated that although PAPs can provide an important safety net to financially needy patients, these programs also present a risk of fraud, waste, and abuse with respect to federal health care programs if they are not independent from donors. *Id.*

93. The OIG noted three more areas of concern related to disease funds, eligible recipients, and the conduct of donors, and required co-payment charities to certify to the OIG that:

a. The co-payment charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states;

b. The co-payment charity will not maintain any disease fund that provides co-payment assistance for only one drug, or only the drugs made or marketed by one manufacturer or its affiliates; and

c. The co-payment charity will not limit its assistance to high-cost or specialty drugs. Instead, the co-payment charity will make assistance available for all products, including generic or bioequivalent drugs covered by Medicare or other insurers, when prescribed for the treatment of the disease state(s) covered by the fund. *Id.*

94. As for the "conduct of donors," the 2014 Bulletin reiterated its prior focus (from the 2005 Special Advisory Bulletin) on co-payment charities not giving a "donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP." *Id.* Notably, the OIG warned that:

> [t]he procedures described in these certifications are a critical safeguard and a material fact upon which we have relied in issuing favorable advisory opinions regarding Independent Charity PAPs. These opinions do not address actions by donors to correlate their funding of PAPs with support for their own products. Such actions may be indicative of a donor's intent to channel its financial support to co-payments of its own products, which would implicate the antikickback statute.

Id.

B. CVC's Growth and OIG's Communications

95. "In 2003 Congress passed the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003, which created Medicare Part D, 'an optional prescription drug benefit . . . which went into effect in 2006.'"[10]

96. With the enactment of Part D, Congress implemented co-pay requirements as a "safety-valve" against supra-competitive pricing.

97. That same year, in 2003, CVC registered for status as a national 501(c)(3) non-profit, charitable organization aimed at providing co-payment assistance for patients with certain chronic or life-threatening diseases. CVC established certain disease funds, including the PAH fund, which were funded by donors, including Actelion.

98. CVC grew from receiving $80,383 from donors in 2004 to receiving over $131 million from donors in 2015.

99. With the increase in CVC donations, came corresponding increases in reported personal compensation and benefits for CVC's executives. **Exhibit 26** – CVC's Form 990 Filings.

100. The personal compensation and benefits reportedly received by CVC's directors, executives, and managers, directly correlated with the amounts of donations CVC received from pharmaceutical manufacturers, including Actelion.

101. CVC violated one of the most basic rules that separates legitimate co-payment charities from illegal ones—it explicitly coordinated with Actelion to steer patients towards Actelion Drugs and provided information to Actelion so that Actelion could correlate its donations with its increased profits on the sale of Actelion Drugs—CVC then repeatedly and continuously lied about this conduct to the OIG.

102. In 2006, CVC certified to the OIG that it would comply with the requirements outlined above in the OIG's 2005 Special Advisory Bulletin. CVC subsequently requested an advisory opinion from the OIG asking whether its "Proposed Arrangement" as a nonprofit, tax-exempt, charitable corporation's proposal to provide financially needy Medicare beneficiaries with assistance and cost-sharing obligations under Medicare Part B, Medicare Part D, Medigap, ***and***

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[10] *Patient Servs., Inc. v. United States*, No. 3:18CV16, 2019 WL 267872, at *4 (E.D. Va. Jan. 18, 2019) (quoting Centers for Medicare & Medicaid Services, History, CMS.gov (last accessed Oct. 17, 2018), https://www.cms.gov/About-CMS/Agency-Information/History/index.html).

Medicare Advantage would constitute grounds for sanctions under certain federal laws, including the AKS. In response, on April 20, 2006, the OIG issued an Advisory Opinion to CVC. *See* OIG, Adv. Op. 06-04 (April 20, 2006), attached as **Exhibit 27**. The 2006 CVC Advisory Opinion noted CVC's certification that, among other requirements, no donor had exerted or will exert "any direct or indirect influence or control" over CVC. *Id.* ("[CVC] has certified that no donor or affiliate of any donor (including, without limitation, any employee, agent, officer shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) has exerted or will exert any direct or indirect influence or control over [CVC] or any of [CVC]'s programs.").

103. The 2006 CVC Advisory Opinion provided that upon request and as a courtesy, donors will be informed monthly of the aggregate number of patients who qualify for assistance in a category, but highlighted CVC's certification that "the monthly data will not contain any information that enable a donor to correlate the amount or frequency of its donation with the number of subsidized prescriptions or orders for its products or the volume or medical condition of patients choosing its services." *Id.* ("No individual patient information will be conveyed to donor, nor will any data related to the identity, amount, or nature of products or services subsidized under the Proposed Arrangement.").

104. The OIG concluded, in part, that "*[b]ased on the facts certified in [CVC's] request* for an advisory opinion and supplemental submissions . . . [and subject to various limitations set forth by the OIG] while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [CVC] under [federal laws regarding civil monetary penalties] in connection with the Proposed Arrangement." *Id.*

105. In December 2015, the OIG published a Modified Advisory Opinion to CVC following the OIG's request that CVC certify compliance with the other factors outlined in the 2014 Bulletin ("2015 CVC Modified Advisory Opinion"), attached as **Exhibit 28**. *See* OIG, Adv. Op. 06-04 (Dec. 23, 2015). The 2015 CVC Modified Advisory Opinion stated that CVC had certified

compliance to each additional factor, and further that CVC had proposed additional modifications to its current operations. *Id*.

106. CVC was admittedly on notice of the OIG's guidance, cautionary language, and the certification requirements set forth in the 2005 and 2014 Bulletins, as wellas the Advisory Opinions OIG provided specifically to CVC. In fact, one of the tactics used by CVC to mislead the OIG (the public, third-party payors, patients, and healthcare providers) was through the creation of a fake "Compliance Program" "to assist CVC in preventing, detecting and responding to illegal, improper and unethical conduct . . . [and to] serve as a procedural framework for enhancing and monitoring compliance with applicable law, regulation, the CVC Code of Conduct and organizational policies and procedures. ***The Compliance Program is based on . . . applicable [OIG] guidance.***" (*See* Summary of the CVC Compliance Program, attached at **Exhibit 29** (emphasis added). In turn, CVC's "Code of Conduct" purports to "describe[] the commitment that [CVC] expects of itself . . . to maintain the highest ethical standards of honesty and integrity as well as to comply with all laws and legal requirements applicable to [CVC], including [OIG] guidance for charitable patient assistance programs and CVC's OIG Advisory Opinion 06-04, as modified, and industry guidance, including the Independent Charitable Patient Assistance Program Code of Ethics ('IPAP Code of Ethics')." (*See* CVC's Code of Conduct, attached at **Exhibit 30**).

107. CVC used the wire and mail to falsely represent to the OIG, the public, healthcare providers, and third-party payors, that it was "dedicated to the following values/ethical principles . . . [among others]":

a. Act with honesty, integrity and objectivity, and in a manner that will merit the continued trust and confidence of patients and stakeholders.

b. Operate independently free from the influence of CVC donors.

c. Comply with all federal, state, and local laws, regulations, and legal requirements applicable to CVC, including OIG guidance for charitable patient assistance programs and CVC's OIG Advisory Opinion 06-04, as modified.

d. Be vigilant in the detection and prevention of potential fraud, waste, or abuse.

e. Promptly investigate and address potential violations of applicable law, regulation, OIG guidance, CVC's Advisory Opinion, IPAP Code of Ethics, this Code, or Company policies and procedures. *Id.*

108. The referenced IPAP Code of Ethics that CVC falsely represented that it would comply with similarly provides that co-payment charities "[o]perate under the auspices of an ongoing compliance with an organization-specific [OIG] Advisory Opinion," and "[o]perate independently, free from the influence of donors," which included "[r]efrain[ing] from providing donors or other entities with information that could permit the correlation of the amount or frequency of donations with the number of patients assisted by the [co-payment charity] who use a donor's products or services or the volume of those products supported by the [co-payment charity]." (*See* IPAP Code of Ethics, attached as **Exhibit 31**).

109. CVC also publicly advertised its services to healthcare providers, patients, third-party payors, and the general public, representing that it operated a legitimate 501(c)(3), independent charity, when in reality, it was serving as a conduit to funnel kickbacks for Actelion.

110. CVC also publicly represented that it was comply with OIG regulations, when it was not, and it knew it was not.

111. Indeed, CVC shared with Actelion the very information it promised it wouldn't share and steered patients in violation of the OIG's general guidance, the OIG's specific guidance to CVC, CVC's certifications to the OIG, CVC's internal "compliance" policies, the FCA, and the AKS.

112. CVC knew that its conduct violated OIG regulations.

113. In November 2017, the OIG rescinded its prior advisory opinions issued to CVC ("2017 CVC Rescission Letter"). *See* OIG, Adv. Op. 06-04 (Nov. 28, 2017), attached as **Exhibit 32**. The 2017 CVC Rescission Letter was based on CVC's "failure to fully, completely, and accurately disclose all material facts to OIG," and CVC's failure to comply with certain factual certifications made to the OIG. *Id.*

114. The Recission Letter stated,

> Specifically, we have determined that, in contravention of the certifications [CVC] made, [CVC]: (i) provided patient-specific datato one or more donors that would enable the donor(s) to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and (ii) allowed donors to directly or indirectly influence the identification or delineation of [CVC's] disease categories."

Id.

115. The 2017 CVC Rescission Letter concluded that:

> [CVC]'s failure to comply with these certifications materially increased the risk that CVC served as a conduit for financial assistance from a drug manufacturer donor to a patient, and thus increased the risk that the patients who sought assistance from [CVC] would be steered to federally reimbursable drugs that the manufacturer donor sold. This type of steering can harm patients and the Federal health care programs, because, for example, patients may be urged to seek, and physicians may be more likely to prescribe, a more expensive drug if co-payment assistance is available for that drug but not for less expensive but therapeutically equivalent alternatives. ***In these circumstances, manufacturers may have greater ability to raise the prices of their drugs while insulating patients from the immediate out-of-pocket effects of price increases, leaving Federal healthcare programs like Medicare (and the taxpayers who fund those programs) to bear the cost.***

Id. (emphasis added).

116. Shortly thereafter, CVC announced that in light of the 2017 CVC Rescission Letter it would not open financial assistance for any disease fund in 2018. **Exhibit 33** – CVC December 2018 Announcement.[11]

117. Instead, in February of 2018, the President of CVC, Greg Smiley, incorporated a new 501(c)(3) charity (Defendant Adira) where CVC began fraudulently conveying CVC's assets and records, as well as Actelion's funds, to the new charity, as further discussed below. **Exhibit 23** – Adira Business Records.

C. The Scheme Permitted Actelion to Charge Supra-Competitive Prices For and Artificially Inflate the Quantity of Actelion Drugs Dispensed

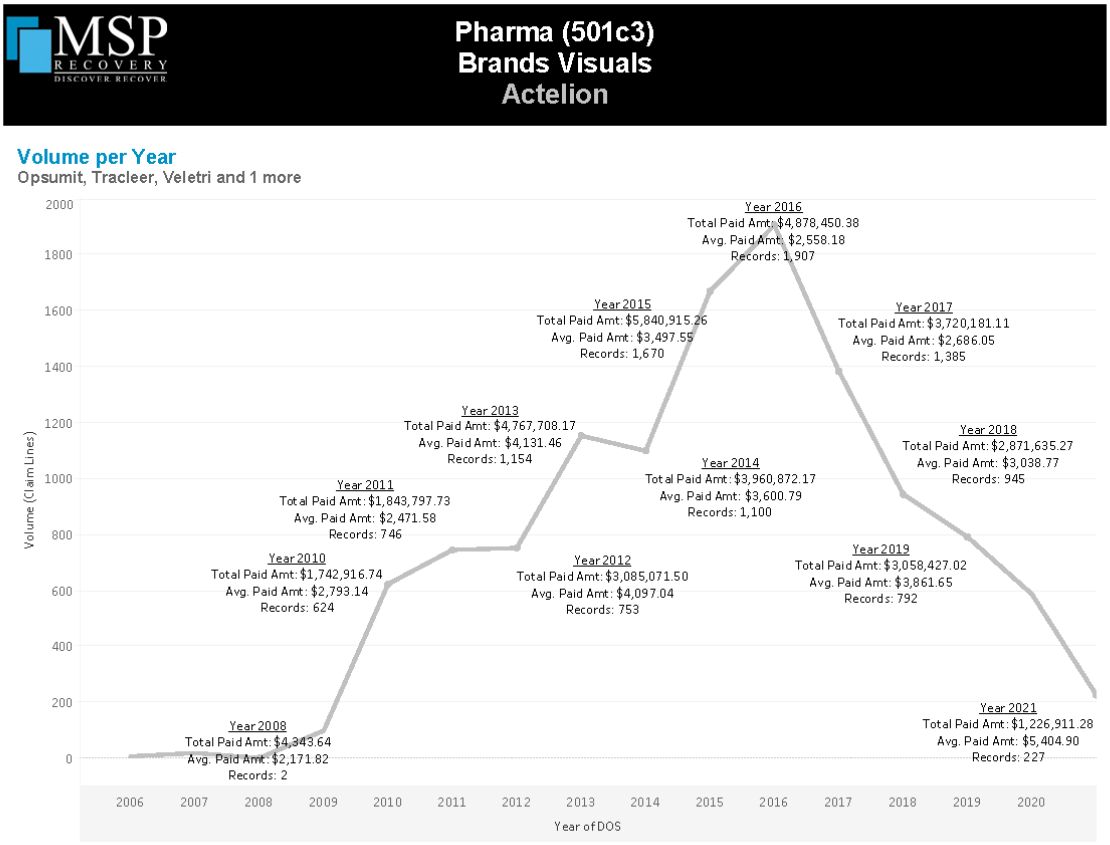
118. As part of the Scheme, Defendants artificially increased the quantity of claims the Assignors and Class Members paid for Actelion Drugs by pushing patients away from Actelion's free drug program "which was open to other financially needy patients, even if those Medicare patients could not afford their copays for Subject Actelion Drugs. Instead, in order to generate revenue from Medicare and to induce purchases of Subject Actelion Drugs, Actelion referred such Medicare patients to the foundation, which allowed the patients' copays to be paid and resulted in

[11] http://www.caringvoice.org/decision-2018-financial-assistance

claims to Medicare for the remaining cost." *See* **Exhibit 2** DOJ Settlement Agreement Press Release. These claims, and all claims for Actelion Drugs during the Scheme, forced the Assignors and Class Members to pay for Actelion Drugs at artificially supra-competitive prices.

119. In and around 2016, the DOJ began issuing subpoenas to Defendants regarding their business practices, donations, and co-payment programs.

120. At that same time, the volume (or quantity) of Actelion Drugs prescribed, dispensed, and paid for by Assignors plummeted, as seen in the chart below.



121. As seen in the chart above, the Scheme allowed Defendants to artificially increase the quantity of Actelion Drugs prescribed and dispensed, for which the Assignors were responsible for payment.

122. Publicly available CMS data reveals a similar pattern.

123. For example, according to CMS data, in 2015, Medicare and Medicaid programs reportedly paid more than $63.2 million for Ventavis. In 2016, Medicare and Medicaid programs reportedly paid $49.3 million, and continued to decline year over year. By 2020, Medicare and Medicaid programs paid at least $13.6 million for Ventavis, a substantial decline since the DOJ first began investigating Defendants' Scheme.

124. Similarly, for Tracleer, in 2015, Medicare and Medicaid programs reportedly paid more than $402.1 million. In 2016, Medicare and Medicaid programs reportedly paid $354 million, and continued to decline year over year. By 2020, Medicare and Medicaid programs paid at least $61.9 million for Tracleer, a substantial decline since the DOJ first began investigating Defendants' Scheme.

125. As seen in Defendants' Financial Reports (*See,* **Exhibits 3 through 21**), during all relevant times, Medicare and Medicaid programs accounted for a substantial proportion of Actelion's total global sales.

126. Further, because Defendants' Scheme violated the AKS, ***all claims*** for the Subject Drugs generated or submitted during the Scheme were unpayable by the Assignors and Class Members pursuant to federal law.

Tracleer

127. Tracleer is used to treat high blood pressure in the lungs (pulmonary arterial hypertension).

128. During the period covered by the DOJ Settlement, Actelion raised the price of its main PAH drug, Tracleer, by nearly ***30 times*** the rate of overall inflation in the United States. This trend continued to increase year over year until at least 2020

129. Medicaid's spending per dosage unit of Tracleer increased approximately 53% between 2012 and 2016. This trend continued to increase year over year until at least 2020

130. The change in average spending by Medicaid per dosage unit of Tracleer increased by 12.4% from 2015-2016 with the annual growth rate in average spending per dosage unit from 2012-2016 increasing by 11.2%. The average spending per dosage unit in 2012 was $99.35, with an average spending per claim totaling $5,578.92. By 2016, the average spending per dosage unit

jumped to $152.02, with an average spending per claim totaling $7,253.49. This trend continued to increase year over year until at least 2020

131. Tracleer Medicare Part D also witnessed a significant rise in cost. Between 2012 and 2016, the average price per dose jumped approximately 37%, resulting in the average spending per beneficiary costing approximately 44% more. This trend continued to increase year over year until at least 2020.

132. Assignors' data for their covered beneficiaries yields similar findings.

Opsumit

133. Opsumit is used to treat high blood pressure in the lungs (pulmonary arterial hypertension).

134. Medicare Part D also witnessed a staggering jump in price during a mere four-year period. From 2013 to 2017, the average spending per beneficiary increased by over ten times. The average spending per beneficiary in 2013 was $7,089 and in 2017, it was $72,616. This trend continued to increase year over year until at least 2020

135. Assignors' data for their covered beneficiaries yields similar findings. Assignors' total amount paid for Opsumit increased from $100,000 in 2013 to $3 million in 2015.

Veletri

136. Veletri is used to treat high blood pressure in the lungs (pulmonary arterial hypertension).

137. Between the years 2016 and 2017, the average Medicare Part D spending per Beneficiary jumped nearly 22%. This trend continued to increase year over year until at least 2020.

138. Assignors' data for their covered beneficiaries yields similar findings. Assignors' total amount paid for Veletri increased from under $100 in 2013 to $74,000 in 2015.

Ventavis

139. Ventavis is used to treat high blood pressure in the lungs (pulmonary arterial hypertension).

140. Medicaid's spending per dosage unit of Ventavis increased by over 100% between 2012 and 2016. Additionally, the average spending per claim increased by approximately 58%

during that same period. This trend continued to increase year over year until at least 2020

141. Medicaid spending per dosage unit of Ventavis was $58.30 in 2012, and $120.54 in 2016. The average spending per claim of Ventavis was $11,173 in 2012, and $17,737 in 2016. This trend continued to increase year over year until at least 2020

142. Assignors' data for their covered beneficiaries yields similar findings. Assignors' total amount paid for Ventavis increased from approximately $100,000 in 2013 to nearly $250,000 in 2015.

143. Actelion's ability to exponentially increase the prices and quantity dispensed of Actelion Drugs year over year would not have been possible but for the illegal Co-Payment Scheme.

D. The DOJ Settlement

144. The DOJ prosecuted Actelion and CVC for their roles in the Scheme, which also defrauded the federal government.

145. This resulted in a settlement in which Actelion agreed to pay $360 million to the United States after the DOJ alleged that Actelion's use of CVC as a conduit violated the AKS and FCA.

146. The DOJ investigation into the Scheme represents one part of a much larger ongoing investigation by the DOJ and OIG, along with the U.S. Attorney's Office for the District of Massachusetts, into schemes by various drug manufacturers and co-payment charities that violated the AKS and FCA.[12] As recognized by pharmaceutical-industry financial analysts, these

[12] Other recent results involving the resolution of AKS and FCA claims brought by the United States against drug manufacturers participating in improper schemes with co-payment charities include: (i) Jazz Pharmaceuticals PLC ("Jazz") agreeing in May 2018 to pay the United States $57 million related to claims involving Jazz's relationship with CVC to fund co-payment for Jazz's narcolepsy drug Xyrem; (ii) United Therapeutics agreed to pay the United States $210 million to resolve the United States' AKS and FCA claims on behalf of Medicare based on United Therapeutics' relationship with CVC; and (iii) Lundbeck LLC agreeing in April 2019 to pay the United States $52.6 million related to claims involving Lundbeck's relationship with CVC to fund co- payment for Lundbeck's Huntington Disease drug, Xenazine.

investigations "impede industry returns."[13]

147. The Actelion Settlement with the United States was based on the DOJ's claims that Actelion's conduct violated the AKS and FCA, thereby leaving Federal healthcare programs (in that case, Medicare Parts A & B) "bear[ing] the cost."

148. The DOJ found that from *at least* January 1, 2014, through *at least* August 2015,[14]

> Actelion used a foundation (CVC) as an illegal conduit to pay the copay obligations of thousands of Medicare patients taking the Subject Drugs and to induce those patients to purchase them, because they knew that the prices Actelion set for the Subject Drugs could otherwise pose a barrier to those purchases. Actelion made donations to the foundation, which, in turn, used those donations to pay copays of patients prescribed the Subject Drugs. Actelion routinely obtained data from the foundation detailing how much the foundation had spent for patients on each Subject Drug; it then used this information to decide how much to donate to the foundation and to confirm that its contributions were sufficient to cover the copays of only patients taking the Subject Drugs. Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their copays for the Subject Drugs.

(*See* **Exhibit 1**– Actelion Settlement)

149. The DOJ further found:

> [A]ctelion routinely obtained data from CVC detailing how many patients on each Subject Drug CVC had assisted, how much CVC had spent on those patients, and how much CVC expected to spend on those patients in the future. Actelion received this information through funding requests, telephone calls, and written reports. Actelion used this information to budget for future payments to CVC on a drug-specific basis and to confirm that its contribution amount to CVC were sufficient to cover the copays of patients taking the Subject Drugs, but not of patients taking other manufacturer's PAH drugs. Actelion had a policy of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients, even if those Medicare patients could not afford their copays for Actelion drugs. Instead, in order to generate revenue from Medicare and to induce purchases of the Subject Drugs, Actelion referred Medicare patients prescribed the Subject Drugs to CVC, which resulted in claims to federal healthcare programs to

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[13] *See Citi Research* ("[t]he ongoing multiple DOJ/OIG investigations into financial donations by pharmaceutical companies to independent foundations has the potential to severely limit future revenues for several high-priced blockbuster Medicare Part D drugs through (i) lowered overall funding for patient out-of-pocket assistance (ii) lesser ability for individual pharmaceutical donors to guide their funding towards specific drugs.").

[14] Although the Actelion Settlement discussed conduct that occurred through August 2015, Plaintiffs have evidence suggesting that the Scheme continued up until, and after, the execution of the Actelion Settlement in December of 2018.

cover the cost of the drugs.

(*See* **Exhibit 2** – DOJ Settlement Agreement Press Release)

150. The Actelion Settlement did not redress the harm that Defendants' Scheme caused to the Assignors and Class Members or settle any claims that the Assignors and Class Members have against Defendants.

151. The Actelion Settlement does not represent the full time span of Defendant's Scheme.

152. Defendants' misconduct caused economic injury to Assignors and the Class Members.

153. Actelion bribed CVC to act as a conduit to illegally pay the co-payment obligations of MA Plan and Medicaid patients taking Actelion Drugs.

154. Defendants' conduct eliminated price sensitivity of patients allowing pharmacies to dispense Actelion Drugs, which in turn enabled Actelion to raise the price of Actelion Drugs to supra-competitive levels, quickly and outside of ordinary market conditions. Assignors and Class Members were left to bear the cost, while CVC was able to show "results" to Actelion Drugs—if Actelion "donated" money to CVC, it would make money, not only off the new "customers" but also by its ability to raise prices, and ensure that the drugs were still prescribed, dispensed, and reimbursed.

155. RICO Defendants' conduct caused MA Plan and Medicaid Plan patients to purchase the Actelion Drugs;

a. Actelion routinely obtained data from CVC detailing how many patients, including MA Plan and Medicaid Plan patients, CVC had assisted and how much CVC had spent on those patients for Actelion Drugs;

b. In deciding whether and how much to donate to CVC, Actelion considered the revenue it would receive from prescriptions for MA Plan patients who received assistance from CVC to cover their co-payments for Actelion Drugs;

c. Actelion used data from CVC to confirm that Actelion's revenue exceeded the amount of Actelion's "donations" to CVC;

d. Actelion ensured that MA Plans and Medicaid Plans bore the cost of Actelion Drugs by employing a policy of not permitting MA Plan and Medicaid Plan patients to participate in Actelion's free drug program (*i.e.*, where government funds are not implicated), which was open to other financially needy patients, even if those MA Plan and Medicaid Plan patients could not afford their co-payments for Actelion Drugs; and

e. Actelion funneled MA Plan and Medicaid Plan patients prescribed Subject Actelion Drugs to CVC, which upon CVC providing coverage of patients' co-payments, triggered Assignors' obligations reimburse for Actelion Drugs.

156. Defendants' Scheme violated the AKS prohibitions on illegal renumeration by Actelion bribing CVC to both (a) illegally funnel funds to certain pharmacies to induce Government payors (such as Assignors and Class Members) to pay for over-priced Actelion Drugs; and (b) to illegally refer, recommend, and arrange for federal healthcare program beneficiaries to receive the Actelion Drugs. 42 U.S.C. § 1320a–7b(b)

157. Defendants also violated the AKS prohibitions on making and causing to be made false statements and representations by Actelion breaching its certifications to comply with the AKS, by causing the prescribing physicians and dispensing pharmacies to submit *per se* false claims to Assignors and Class Members, and by concealing and failing to disclose the illegal renumerations that rendered these claims false while also receiving payment for such claims. 42 U.S.C. § 1320a–7b(a)

158. Therefore, *all claims* for the Actelion Drugs generated or submitted during the course of the Scheme were disqualified from being paid for by Assignors and Class Members.

159. But-for Defendants' conduct, Assignors and Class Members would not and could not have paid for any Actelion Drugs.

160. Because of Defendants' Scheme, Assignors and Class Members paid for prescriptions they would not have otherwise paid and there was a direct relationship between the misconduct at issue here and the payments Assignors and Class Members made for Enrollees. Such payments involved reimbursement of illegal and unpayable claims, artificially increased quantities of prescribed and/or dispensed Actelion Drugs, and supra-competitive prices on all Actelion Drugs prescriptions.

161. RICO Defendants knew and intended that their Scheme would generate disqualified claims and artificially inflate the quantities of prescribed and/or dispensed Actelion Drugs and allow Actelion to raise the prices of Actelion Drugs to supra-competitive levels.

162. At relevant times herein, Defendants (their agents and conspirators) actively and falsely marketed to and misled health care providers, third-party payors, governmental agencies, and the public, regarding the legitimacy of their Co-Payment Scheme, tainting any and all claims for Actelion Drugs submitted during the course of the Scheme.

163. Assignors and Class Members were the primary and intended victims of Defendants' Scheme. The injury to the Assignors was a foreseeable and natural consequence of the Scheme because Actelion knew that third-party payers such as the MA Plans and the Medicaid Plans would pay for or reimburse the cost of Actelion Drugs.

164. Assignors and Class Members suffered direct economic injury as a direct and proximate cause of Defendants' Scheme and are therefore best suited to advance and pursue the recovery of the claims asserted in this Complaint.

165. In fact, Assignors and Class Members are likely the only entities harmed by Defendants' Scheme.

166. Indeed, wholesale distributors, specialty distributors, and/or pharmacies actually benefit from the scheme as their sales increase *because the rate of abandonment decreases*, their *co-payment revenue increases,* as well as revenue from service fees, some of which are based on a percentage of the Wholesale Acquisition Cost ("WAC").[15, 16]

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[15] Prescription abandonment—when a prescription is transmitted to the pharmacy but never filled—is a major concern for both providers and drug manufacturers. Prescription abandonment is multi-faceted, but it is widely understood that high co-payments are a leading cause and lowering co-payments significantly reduces abandonment for highly effective chronic treatments. Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*. 298.1 Jama 61, 61-69 (2007). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375697/

[16] Prescription abandonment causes an estimated 125,000 avoidable deaths in the U.S. annually. Regardless of whether patients and doctors are induced by PAP funds at the prescription stage, the data is clear that patients are induced by co-payment assistance at the dispensing stage. Hayden B. Bosworth et al., *Medication Adherence: A Call for Action*. 162.3 Am Heart J. 412 (2011). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/

167. Actelion knows or has reason to know that prescription abandonment and low medication adherence (i.e., taking the prescription as prescribed) are serious issues in treating PAH.[17, 18] High co-pay costs for patients is a major contributing factor to both abandonment and low adherence.[19] Instead of lowering the cost of its PAH medication or allowing federal healthcare program beneficiaries to access its free drug program, Actelion chose to run an illegal and lucrative scheme to force Assignors and Class Members to shoulder the burden of its greed.

168. Defendants had the shared goal of, among other illicit objectives, maximizing the amount of sales for Actelion Drugs and growing Actelion's co-payment assistance fund, thereby enabling CVC's directors and officers to use the non-profit charities increased funds to justify a surge in their own compensation and luxurious lifestyle. The Co-payment Scheme increased the number of MA Plan and Medicaid Plan patients (among all healthcare programs) who were receiving co-payment assistance for Actelion Drugs from Actelion's co-payment fund, triggering the Assignors' and Class Members' coverage obligations for these Enrollees, eliminating price sensitivity to Actelion, and allowing Actelion to increase its revenues and profits related to Actelion Drugs sales.

169. For Defendants, this collusive bribery Scheme was a "win-win" arrangement. Actelion systematically blocked MA Plan and Medicaid Plan beneficiaries from accessing Actelion's free drug program. Instead, Actelion referred those beneficiaries to CVC. Actelion directed its bribes to CVC with the intent to increase MA Plan and Medicaid Plan reimbursements. Part of those bribes were made to CVC in order for CVC to enroll patients in state and federal

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[17] Stephen Mathai et al., *Low Utilization of Prostacyclin Therapy Prior to Death Among Medicare Patients with Pulmonary Arterial Hypertension*, Vol. 158 Chest J. 4 (2020). Available at https://journal.chestnet.org/article/S0012-3692(20)34047-2/fulltext

[18] Duncan Grady et al. *Medication and patient factors associated with adherence to pulmonary hypertension targeted therapies.* 2018 Pulm Circ. 8(1), (2018). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5731720/. Over 6% of the study sample was below 80% adherence over a two-year period, resulting in a significant increase in reported adverse events. Nisha B. Shah et al. *High rates of medication adherence in patients with pulmonary arterial hypertension: An integrated specialty pharmacy approach*, PLOS ONE 14(6): e0217798, (2019). Available at https://doi.org/10.1371/journal.pone.0217798

[19] *See* footnotes 16 and 17, *supra*.

health care plans, while other parts were made to CVC in order for CVC to provide quarterly reports to Actelion regarding the Actelion Drugs.

170. As CVC illegally provided data and information to Actelion related to the profitability of Actelion's "donations" to CVC, Actelion would couple their use of CVC with price increases of Actelion Drugs. Actelion's bribes to CVC resulted in more MA Plan and Medicaid Plan patients receiving co-payment assistance. This in turn eliminated price sensitivity for Actelion Drugs, resulting in supra-competitive pricing and artificially inflated quantities of dispensed Actelion Drugs, which together increased profits for all Defendants and their executives. And all along the way, as Actelion's drug prices increased and utilization of CVC increased to mask the effects of the price increases, donations to CVC continued to rise, and Defendants' executives continued to pocket more and more illicitly generated profits for themselves. *See*, **Exhibits 3 through 21**; **Exhibit 26**.

171. Data from CMS and Assignors show how Defendants' Scheme eliminated price sensitivity of patients purchasing, physicians prescribing, and pharmacies dispensing Actelion Drugs and resulted in federal healthcare programs bearing the increased costs. This data reflects that Actelion charged supra-competitive prices and increased the quantity of Actelion Drugs paid for by federal programs while the Co-Payment Circumvention Enterprise pursued such goals through unlawful means, as described herein.

172. Assignors paid approximately $31 million in claims for Actelion Drugs from January 1, 2014, *until present*. Information in the exclusive control of Defendants will show that a significant portion of the co-payments paid on behalf of the beneficiaries of the Assignors and Class Members were made by CVC as a result of Defendants' Co-payment Scheme.

173. Assignors were not privy to which patients' co-payments were related to Actelion's bribes to CVC. Assignors' obligations to cover claims for Actelion Drugs only arose after CVC unlawfully funneled Actelion funds to certain pharmacies.

174. Evidence suggests that most, if not all, of the pharmacies that dispensed the Actelion Drugs during the relevant time period, were aware of, participated in, and/or recklessly disregarded the fact that Actelion used CVC as a conduit in violation of the AKS, resulting in millions of co-

payment revenue paid by Actelion through CVC to the pharmacies.

175. As a result of Defendants' fraudulent concealment of their Scheme, Assignors did not and could not have known that their reimbursement obligations, or the supra-competitively priced drugs, were caused by Defendants' misconduct.

176. Defendants' documents and disclosures clearly show that they possess information to show exactly which patients received co-payment assistance.

177. For example. CVC's Form 990 Tax Filings state in Supplemental Information to Schedule I, Part I, Line 2:

> Financial grants are given when an individual specifies he/she has adisease supported by Caring Voice and he/she meets stated income guidelines. Individuals fill out an application for financial assistance which must be accompanied by a medical certification from their physician documenting their diagnosis. Grant funds are paid to third party pharmacies or insurance companies after proof is received that the patient has incurred therapy costs associated with the specific diagnosis. ***Caring Voice monitors the use of grant funds for individuals using proprietary database software. The database maintains all records to substantiate the amount of an individual's grant, the grantee's eligibility and payments made onthe grant***.[20]

178. CVC's Code of Conduct (adopted by CVC's Board of Directors on July 22, 2017) states that CVC will:

> Maintain accurate and complete books and records, including accounting and financial data, and retain such books and records in accordance with applicable federal, state and local laws and regulations, Company's record retention policies and procedures and Company instructions.[21]

179. As noted above, RICO Defendants' Scheme benefited CVC and its executives.

180. In addition, Actelion intentionally concealed the Scheme, covering up the true nature of its payments and relationship with charities. The payments were in fact bribes and for the purpose of using the foundations as conduits to effectuate its goals of artificially and deceptively inflating the drug prices and increasing the use of the drugs to increase profits at the expense of healthcare payors like Assignors and Class Members. Actelion's concealment prevented Plaintiffs from reasonably discovering the facts underlying Defendants' Scheme which caused Assignors' and

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[20] *See* CVC's Form 990 Tax Filings, attached as **Exhibit 26**.
[21] *See* CVC's Code of Conduct, attached as **Exhibit 30**.

the Class Members' injuries. In other words, Actelion's concealment lulled Plaintiffs into inaction, resulting in substantial damages to Plaintiffs' property and business over the course of the illegal scheme.

181. Defendants' Scheme caused pharmacies to seek reimbursement from federal health care programs for their purchases of Actelion Drugs. Not only are physicians and pharmacies required to explicitly certify compliance with the AKS, but the act of submitting claims for reimbursement carries with it an implied certification of compliance with governing federal rules that are a precondition of or material to payment. Pharmacies submitting claims for reimbursement therefore certified compliance with federal law, including the AKS. Defendants thus caused pharmacies to provide false certifications.

182. Upon information and belief, some pharmacies involved in the Scheme knowingly provided false certification to Assignors and Class Members.

183. Upon information and belief, discovery will likely reveal that certain pharmacies conspired with Defendants to achieve the objectives of the Co-Payment Scheme, thereby contributing to the billions of dollars in yearly "co-payment revenue" received by those pharmacies.

184. As Actelion used CVC as a conduit, CVC did not act as an independent charity. Instead, Defendants' conduct violated the AKS, OIG regulations, and state and federal laws, rendering any certification relating to the Actelion Drugs as false, and any claim for reimbursement unpayable by Medicare and Medicaid programs (such as Assignors and Class Members).

185. As a result of Actelion's collusion with and unlawful use of CVC as a conduit, the Assignors and Class Members were harmed by paying for claims that were unpayable, which they would not have paid but for RICO Defendants' concealment of their scheme.

186. As a direct result of the Co-payment Scheme, Assignors and Class Members also paid for an increased number of Actelion Drugs prescriptions throughout the United States.

187. As a direct result of the Co-Payment Scheme, Assignors and Class Members also paid supra-competitive prices for the Actelion Drugs. Such prices would not have been possible but-for Defendants' Scheme.

188. Following CVC's announcement in 2018 that it was discontinuing operations, CVC

contacted Actelion to transfer approximately $10 million to Adira.

189. By then, Johnson and Johnson owned Actelion. **Exhibit 34** – J&J 2017 10-K; **Exhibit 35** – J&J 2018 10-K; **Exhibit 36** – J&J 2019 10-K; **Exhibit 37** – J&J 2020 10-K; **Exhibit 38** – J&J 2021 10-K.

190. Upon information and believe, starting in 2019, Adira joined the Co-Payment Circumvention Enterprise, assumed the role of conduit from CVC, partnered with Actelion, and engaged in overt acts in furtherance of the scheme to defraud Assignors and Class Members

E. CVC's Fraudulent Transfers to Adira

191. As stated above, in or around November of 2017, the OIG issued the 2017 CVC Rescission Letter.

192. On February 20, 2018 (just months after the 2017 CVC Rescission Letter), CVC's President and Chairman together incorporated a new 501(c)(3) charity—Facilitating Patient Health, which was later renamed to Adira—to continue using the same fraudulent funds in furtherance of the Scheme.

193. During this time, CVC was aware of, and involved in, several DOJ investigations and settlements for fraudulent and illegal acts at issue in this Complaint.

194. On December 6, 2018, the DOJ announced that it had entered into a settlement agreement with Actelion regarding its fraudulent conduct with CVC. **Exhibit 2.**

195. That same month, CVC publicly announced that it was discontinuing operations, which was false. **Exhibit 33**.

196. Instead, CVC's management simply transferred millions in assets to themselves, through Adira, and then publicly claimed to be defunct. *See* **Exhibit 22** – CVC Articles of Dissolution.

197. In fact, between at least 2011 and 2017 Greg Smiley served as treasurer of CVC. Starting sometime in 2016 or 2017, Greg Smiley became the President and CEO of CVC and held that position until the end of CVC's disillusionment. **Exhibit 22, 26** - CVC Form 990s.

198. Similarly, in 2014, James Rock became a director and member of the executive team

at CVC. Starting in 2016, James Rock was elevated to Chairman of CVC and held that position until the end of CVC's disillusionment. **Exhibit 22, 26** - CVC Business Records & Form 990s.

199. On February 23, 2018, (just months after the 2017 CVC Rescission Letter), CVC's President Greg Smiley and Chairman James Rock together incorporated a new purported 501(c)(3) charity—Facilitating Patient Health ("FPH"), which was later renamed to Adira—to continue operating some of the same disease funds that CVC was forced to close. James Rock and Greg Smiley were named as two of the three founding directors. *See* **Exhibit 22, 23** – Adira Business Records & Form 990s.

200. FPH's 2019 Annual Report (submitted February 9, 2019) names James Rock as Director and Greg Smiley as Director and Chief Executive Officer.

201. On March 15, 2019, CVC entered into a Grant Agreement with FPH. ("CVC-FPH Agreement"). Greg Smiley—who was President of both CVC and FPH at the time—signed on behalf of CVC, while James Rock—who was Chairman of both CVC and FPH at the time—signed on behalf of FPH.

202. The CVC-FPH Agreement provided that CVC would provide $3,000,000 to FPH.

203. On May 6, 2019, FPH amended its articles of incorporation (signed by Greg Smiley) to change the organization's name to "Adira Foundation."

204. On May 31, 2019, CVC entered into a "Records Transfer Agreement" with Adira, where CVC would "transfer title and custody of all electronic patient records . . . as well as certain other records" to CVC. The Records Transfer Agreement contains an attached "Bill of Sale" which purports that, in consideration of the agreement, Adira paid CVC $10.

205. Greg Smiley signed the Records Transfer Agreement on behalf of ***both*** CVC ***and*** Adira. No other signatures appear on the Records Transfer Agreement. In addition to Greg Smiley and James Rock, several CVC employees—including other senior management personnel—began working for Adira at the same time as the transfers. For example, Lauren Ruiz was Director of Patient Services at CVC from November 2011, until joining Adira in April 2019 as a Programs Manager. Additionally, Bruce Packett, who served as a director at CVC for several years, including from 2017-2020, has now also served on Adira's Board of Directors since 2018.

206. CVC and Adira even used the same accounting firm, Meadows Urquhart Acree & Cook LLP, to file their respective 2019 990 forms.

207. Plaintiffs are in possession of further evidence of CVC fraudulently conveying its assets to Adira, and Adira taking overt acts in furtherance of the Scheme.

208. In fact, in July of 2019, CVC continued communicating with Actelion, informing Actelion that it was continuing operations and Adira, and requesting Actelion's consent to transfer approximately $10 million of Acetlion's funds to Adira.

209. Adira then began using the mail and wires to correspond with Actelion, in furtherance of the Scheme.

210. Additionally, an internal CVC document titled "CVC Board Slides 202004" reveals that CVC transferred all non-restricted and unobligated funds to Adira, noting that "$4.0 million Total Will be transferred to Adira on or before 6/30/2020." In addition, this same document instructs that CVC will transfer to Adira both cash and "safe assets earning 5+%."

211. Further, several additional internal CVC documents instruct that an extensive list of personal property was (or would be) given to Adira, including laptops, computer servers, software licensees, office equipment, etc.

212. Greg Smiley's salary from CVC in 2018 was $190,309. In 2019, Greg Smiley's 2019 CVC salary was $256,066 and $192,865 in 2020. *See* **Exhibit 26** - CVC Form 990. In addition to his CVC salary, Greg Smiley was paid, by Adira, $192,865 in 2019 and $234,248 in 2020. *See* **Exhibit 23** – Adira Form 990s.

V. CLASS ACTION ALLEGATIONS

213. At all material times, Actelion Drugs—manufactured and sold by Actelion—were shipped across state lines and sold to customers located both within and outside its state of manufacture.

214. During the relevant time period, in connection with the purchase and sale of Actelion Drugs, monies, as well as contracts, bills, and other forms of business communication and transactions, were transmitted in continuous and uninterrupted flow across state lines.

215. During the relevant time period, various methods of communication were used to effectuate the illegal acts alleged here, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as alleged in this Complaint, were within the flow of, and have substantially affected, interstate commerce.

216. Plaintiffs bring this action on behalf of themselves and the following Class Members:

Federal RICO / State RICO / State Consumer Protection Statute Class 1:

> All Medicare Advantage Organizations, Medicaid Managed Care Organizations, and at-risk, first-tier, and downstream entities in the United States and its territories that from at least January 1, 2014 through present, pursuant to Medicare and/or Medicaid contracts offering Medicare and Medicaid benefits, provided services, purchased Subject Actelion Drugs, provided reimbursement, or possess the recovery rights to reimbursement for some or all of the purchase price of the Actelion Drugs resulting from CVC's or Adira's co-payment assistance. This class excludes: (a) RICO Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and any members of their immediate families.

Federal RICO / State RICO / State Consumer Protection Statute Class 2:

> All self-funded, third-party payors and related entities in the United States and its territories that from at least January 1, 2014 through present, provided services, purchased the subject pharmaceuticals, provided reimbursement, or possess the recovery rights to reimbursement for some or all of the purchase price of Actelion Drugs resulting from CVC's or Adira's co-payment assistance. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and any members of their immediate families.

217. Plaintiffs bring this action pursuant to Federal Rule of Civil Procedure 23 both individually and on behalf of a national damages class.

218. As discussed in this Complaint, Defendants' Scheme resulted in increased sales of the Actelion Drugs, the cost of which were borne by Assignors and Class Members. All members of the class are subject to the same AKS compliance requirements and are all prohibited from paying for or reimbursing claims that are unpayable due to AKS violations. The damages suffered by Plaintiffs apply to all individual Class Members (and Plaintiffs as the rightful assignees of those

organizations that assigned their rights to Plaintiffs). Class action law has long recognized that, when companies engage in conduct that has uniformly harmed a large number of claimants such as Plaintiffs and other third-party payers, class resolution is an effective tool to redress the harm.

219. Assignors and Class Members have been deprived of money as a result of their obligation to pay for prescribed the Actelion Drugs at artificially inflated quantities and supra-competitive prices, and because of RICO Defendants' improper shifting of patients from Actelion's free drug program to the co-payment charity. But for the Scheme, Assignors and Class Members would have paid far less for the Actelion Drugs.

220. The Classes, defined above, are properly brought and should be maintained as a nationwide class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy:

> Numerosity: The Class Members are so numerous that joinder is impracticable. Plaintiffs believe the Class includes thousands of third-party payors that paid for hundreds of thousands, if not millions, of prescriptions. There are thousands of entities (including the organizations that assigned their rights to Plaintiffs) throughout the United States that sustained damages as a result of their payment for the Actelion Drugs caused by Defendants' Scheme. Thus, the numerosity element for class certification is met.
>
> Commonality: Defendants' misconduct was directed at all Class Members. Questions of law or fact are common to all Class Members. Defendants' co- payment assistance conspiracy Scheme and racketeering activity carried out by their enterprise have a common, adverse effect on all Class Members. Thus, common questions of law or fact are prevalent throughout the class, such as whether Defendants engaged in a pattern of racketeering activity and conspired to induce Class Members' payment for the Actelion Drugs prescriptions. Each Class Member shares the same needed remedy—namely reimbursement for unlawfully paid bills and lost money or disgorgement of Defendants' profits as a result of Defendants' Scheme and racketeering activity that caused Assignors and Class Members to pay supra-competitive prices for artificially inflated quantities of the Actelion Drugs.
>
> Typicality: Plaintiffs' claims are typical of the claims of the Class Members because their claims arise from the same course of conduct by Defendants, namely Defendants' formation of their co-payment Scheme and racketeering activity unlawfully causing Class Members to reimburse pharmacies for the over-prescription and over-dispensing of the Actelion Drugs at supra- competitive prices and actual payment that would otherwise not have been made but for Defendants' conduct. Plaintiffs' claims are, therefore, typical of the Class Members.
>
> Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of

the Class Members. Plaintiffs' interests in vindicating these claims are shared with all of the Class Members. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action litigation and have particular experience with class action consumer protection and RICO litigation in the pharmaceutical industry.

221. The Class is properly brought and should be maintained as a class action under Rule 23(b) because a class action is the superior method for resolving these claims. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Classes. Defendants deliberately conspired to cause Assignors to pay for the Actelion Drugs through the formation of the Scheme that subsequently resulted in the submission and payment of supra-competitive prices for the Actelion Drugs by Assignors and the Class Members that otherwise would not have been paid.

222. Assignors and Class Members paid for prescriptions of the Actelion Drugs that they otherwise would not have paid but for Defendants' Co-payment Scheme and racketeering activity.

223. Additional questions of law and fact common to some or all the Classes include, but are not limited to:

a. Whether Defendants engaged in a bribery and/or kickback scheme and thereby violated the AKS, the Travel Act, and/or mail and wire fraud statutes;

b. The effect of such bribery and/or kickback scheme on the quantities dispensed and prices of the Actelion Drugs; and

c. The quantum of overcharges paid by Assignors and Class Members in the aggregate.

224. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

225. Plaintiffs know of no difficulty to be encountered in this action that would preclude

its maintenance as a class action.

VI. TOLLING OF THE STATUTE OF LIMITATIONS

Fraudulent Concealment Tolling

226. The claims asserted in this Complaint have been tolled as a matter of law as Defendants took affirmative steps to conceal the wrongful conduct alleged herein including, *inter alia*, Actelion utilizing CVC as a conduit and concealing such use under the guise of "donations" to an "independent" co-payment assistance charity.

227. The claims asserted in this Complaint have been tolled as a matter of law as CVC took affirmative steps to conceal the wrongful conduct alleged herein by misleading the OIG, DOJ, health care providers, certain pharmacies, beneficiaries, third-party payors, and the general public, into believing it was operating a legitimate, legal, and independent 501(c)(3) charitable organization, when in reality, it was serving as an illegal conduit for certain manufacturers, including Actelion.

228. The claims asserted in this Complaint have been tolled as a matter of law as CVC and Adira took affirmative steps to conceal the wrongful conduct alleged herein including, *inter alia*, CVC's fraudulent transfers to Adira and concealing such transfers as bona fide transactions.

Continuing Violation Doctrine

229. The Complaint alleges a continuing course of conduct, and Defendants' unlawful conduct has inflicted continuing and accumulating harm. Defendants' unlawful conduct and the accumulating harm to the Assignors did not end alongside the DOJ Settlement Agreements. Accordingly, Plaintiffs can recover for damages that they suffered during any applicable limitations period.

Discovery Rule Tolling

230. Assignors did not know, and had no reasonable way of discovering, Defendants' alleged Scheme until it became public knowledge.

231. Within the applicable statutes of limitation, Assignors could not have discovered through the exercise of reasonable diligence that Defendants were concealing the conduct alleged

herein.

232. Assignors did not discover, and did not know of, facts that would have caused a reasonable person to suspect that Defendants were engaged in the alleged Scheme, nor would a reasonable diligent investigation have disclosed the true facts.

233. Assignors did not know, and had no reasonable way of discovering, CVC's and Adira's fraudulent and/or voidable transfers.

234. Within the applicable statutes of limitation, Assignors could not have discovered through the exercise of reasonable diligence that CVC and Adira were concealing their conduct alleged herein. The Assignors did not discover, and did not know of, facts that would have caused a reasonable person to suspect that CVC and Adira were fraudulently transferring assets, nor would a reasonable diligent investigation have disclosed the true facts.

Equitable Tolling

235. Defendants were under a continuous duty to disclose to Assignors and Class Members the existence and true nature of the Co-payment Circumvention Enterprise, including the subsequent obligations for payment triggered by Defendant's misconduct.

236. The existence of Defendants' co-payment assistance scheme was a material fact, and Defendants concealed its existence and instead falsely represented that they were in compliance with federal regulations including the FCA and AKS. When Defendants made these misrepresentations and concealed their co-payment assistance conspiracy scheme, they had knowledge of the facts surrounding the scheme's existence. Defendants concealed the co-payment assistance conspiracy scheme and made misrepresentations about it with the intention that Assignors and Class Members would rely on said misrepresentations and would pay for the Actelion Drugs. Defendants' concealment induced Assignors and Class Members to reasonably rely and act upon these misrepresentations and were misled into paying for the Actelion Drugs Drugs. *See Safe Env't of Am., Inc. v. Emps. Ins. of Wausau,* 278 F. Supp. 2d 121, 126–27 (D. Mass. 2003).

237. Based on the foregoing, Defendants are estopped from relying on any statutes of limitations in defense of this action and all equitable principles of tolling should apply

VII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
Violations of Racketeering Influenced Corrupt Organization Act ("RICO") 18 U.S.C. § 1962(c) Through the Use of Co-Payment Charity Scheme
Against All Defendants

238. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

239. At all relevant times, RICO Defendants have been "persons" under 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through the pattern of racketeering activity detailed throughout this Complaint in violation of 18 U.S.C. § 1962(c).

240. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

241. Section 1964(c) provides that "any person injured in his business or property by reason of a violation of section 1962 of this chapter may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee." The elements of a RICO claim under § 1964(c) pursuant to a violation of§ 1962(c) are: (i) conduct; (ii) of an enterprise; (iii) through a pattern of; (iv) racketeering activity.

Description of the Co-payment Circumvention Enterprise

242. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

243. Under 18 U.S.C. § 1961(4), a RICO "enterprise" may be an association-in-fact that, although it has no formal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprises' purpose.

244. The Co-payment Circumvention Enterprise is an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), consisting of RICO Defendants Actelion, CVC, and Adira,

including their employees and agents.

245. The Co-payment Circumvention Enterprise functioned as an ongoing and continuing unit. The Co-payment Circumvention Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of the Enterprise participants is a "person" distinct from the Enterprise.

246. The Co-Payment Circumvention Enterprise had a common purpose that united its members. One purpose was to steal funds from the Medicare Trust Fund. Another purpose was to generate personal profits for Defendants' executives from unlawful bribes and kickbacks.

247. Defendants' common purposes were accomplished by, among other things, (1) growing CVC's fund and CVC's executive compensation; (2) eliminating price sensitivity for patients and health care providers; (3) misleading government agencies, third-party payors, health care providers, and beneficiaries regarding the legitimacy of CVC's operations and its conduct; (4) funneling patients towards and then away from Actelion's free drug program; (5) applying to Medicare and Medicaid programs on behalf of beneficiaries; and (6) violating OIG regulations and providing data to allow Actelion to conduct continuous ROI calculations, all of which resulted in the unlawful depletion of state and federal dollars, increased the number of patients who had their drugs purchased by Assignors and Class Members, and increased the personal gains received by Defendants' executives through the payment of AKS-tainted claims and drugs at supra-competitive prices.

248. By funneling and steering people into CVC's fund, and applying for and obtaining state and federal coverage for individuals, the Co-payment Circumvention Enterprise increased Actelion's number of covered "customers," thereby triggering the Assignors' and Class Members' coverage obligations for their Enrollees and eliminating price sensitivity to the Actelion Drugs.

249. Defendants each received substantial revenue from participating in the Co- Payment Scheme. Such revenue was exponentially greater than it would have been in the absence of such Scheme.

250. Each portion of the Co-payment Circumvention Enterprise benefitted from the existence of the other parts.

251. The Co-payment Circumvention Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Defendant.

252. There were interpersonal relationships between those associated with the Co-payment Circumvention Enterprise. This includes relationships: (1) among CVC's officers, agent, and directors and relationships among Actelion's officers, directors, principals, and agents; (2) among CVC and Actelion; (3) among CVC's officers, agents, and directors and Adira's officers, agents, and directors; and (4) among Actelion's officers, directors, principals, and agents, and Adira's officers, agents, and directors. This is evidenced by, among other things, the routine communications (through the U.S. Mail and Wire) between Defendants to enable execution of the Scheme. For example, by sharing data with Actelion (in exchange for bribes), CVC enabled Actelion to track and monitor its "donations" to ensure that its payments achieved their proper purpose of paying co-pays only for patients receiving the Actelion Drugs, thereby substantially depleting state and federal funds and increasing profits for Actelion.

253. The OIG explicitly warned CVC not to send pharmaceutical manufacturers this information because doing so would violate the AKS and FCA, and CVC certified its understanding and compliance with the OIG's warnings. But Defendants participated in this conduct anyway. Actelion settled the DOJ's AKS and FCA claims for $360 million for them harm this Scheme caused the DOJ.

254. The Co-payment Circumvention Enterprise had the longevity sufficient to permit its associates to pursue the enterprise's purpose. It lasted for years, during which time its purposes were pursued. CVC grew its fund for the Actelion Drugs as Actelion increased its annual "donations" to CVC. And Defendants' officers and directors increased their annual compensation, year over year. *See* **Exhibits 15 through 23, 26.**

255. Actelion carried out its business activities both with and without CVC. Similarly, CVC operated other funds without Actelion. The Scheme thus did not involve parallel conduct because Defendants participate in transactions with co-payment charities that do not result in violations of the AKS, FCA, RICO, Consumer Protection Laws, OIG regulations, or other state and

federal laws.

Conduct of the Enterprise's Affairs

256. Each Defendant conducted or participated in, either directly or indirectly, the conduct of the Co-payment Circumvention Enterprise's affairs. Each Defendant was part of the Co-payment Circumvention Enterprise and each operated and managed the Co-payment Circumvention Enterprise. Such participation included, but is not limited to: (1) CVC managing, collecting, and sharing data (through the U.S. mail and wire facilities) with Actelion so that Actelion could effectively conduct ROI analyses on the amounts of "donations" to CVC's PAH Fund; (2) Actelion providing bribes and kickbacks, disguised as donations, to CVC so the payment obligations of the Assignors and Class Members would be triggered; (3) CVC and Actelion steered and funneled theActelion Drugs patients to CVC's PAH Fund; and (4) Adira assuming CVC's role and enabling the continuation of the Scheme after CVC's fraudulent operations were covered by the DOJ, stripping CVC of its ability to continue operating as a 501(c)(3) charity.

257. At all relevant times, each Defendant was aware of the Co-Payment Circumvention Enterprise's conduct and was a knowing and willing participant in the racketeering conduct of the Enterprise.

Defendants' Pattern of Racketeering Activity

258. To carry out their illegal and collusive bribery Scheme Defendants knowingly conducted or participated, directly or indirectly, in the affairs of the Co-payment Circumvention Enterprise through a pattern of racketeering activity within the meaning of 18U.S.C. §§ 1961(1), 1961(5), and 1962(c), and employed the use of the mail and wire facilities, in interstate commerce, to promote, manage, establish, and carry out the Co-Payment Circumvention Enterprise in violation of 18 U.S.C. § 1952 (Travel Act), § 1341 (Mail Fraud), and § 1343 (Wire Fraud).

259. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mail or interstate wire facilities to further the Co-Payment Circumvention Enterprise. Each of these mailings and interstate wire transmissions constitutes an instance of "racketeering activity" under 18 U.S.C. § 1961(1)(B) by violating the underlying predicate acts of § 1952, § 1341, and § 1343. Collectively, these violations constitute a

"pattern of racketeering activity," under 18 U.S.C. § 1961(5), to advance Defendants' intentional and illegal Scheme.

260. Defendants engaged in a scheme to illegally profit at the direct expense of third-party payors, including the Assignors and Class Members. Defendants steered patients into CVC's funds for the Actelion Drugs, knowing third-party payors such as Assignors and Class Members would ultimately bear the cost for the Actelion Drugs. Defendants knew their Scheme to funnel, steer, and refer patients and funds were violations of federal and state laws including, but not limited to, the AKS and the FCA and that they were transmitting false and illegal information through mail and wire communications.

261. Defendants' use of the mails and wires to perpetuate their Scheme involved thousands of communications which included, among others, the following:

a. Communications from Actelion and CVC to patients, steering them to Actelion's co-payment assistance program using CVC;

b. Transmittal of bribes, disguised as donations, by Actelion to CVC;

c. Transmittal of kickbacks, disguised as donations, by Actelion to CVC and pharmacies;

d. Submission of certifications by Actelion and CVC in which they claimed to be in compliance with federal law, including the AKS and FCA;

e. Submissions of data from CVC to Actelion so that Actelion could determine how much money it was making from its "donations" to CVC and how much more money it could make by increasing its "donations";

f. Certifications by CVC that it would determine the eligibility according to a "uniform measure of financial need that is applied in a consistent manner" when in fact CVC emphasized patients taking the Actelion Drugs based on Actelion bribes, not financial need;[22]

g. Causing false claims, in violation of the FCA and AKS, to be submitted by complicit, and non-complicit, pharmacies to Assignors and Class Members; and

h. Using the mail and wire to mislead the government agencies (i.e., the OIG, IRS, DOJ and state departments of record) through false certifications and misrepresentations; and

i. Fraudulently conveying ill-gotten gains to Adira and then using the mail and wire to advertise and market Adira's services; and

j. Misleading third-party payors, health care providers, investors, government

[22] *See* CVC's Form 990 Filing, attached as **Exhibit 26**.

agencies, and the general public into believing the legitimacy of Defendants' Scheme.

262. Defendants violated the Travel Act by using the mail and wire facilities to commit, promote, manage, establish, and carry on their bribery and/or kickback scheme in violation of the laws of the United States, namely, the AKS. Defendants further used the mail and wire facilities to distribute the proceeds of their bribery and/or kickback scheme.

263. The predicate acts violating the Travel Act, as well as mail and wire fraud, had the same purpose: to make money by growing CVC's funds as large as possible so that CVC's officers and directors could pay themselves millions, and so that Actelion could get as many "customers" as possible for the Actelion Drugs at the expense of the Assignors and Class Members.

264. All of the predicate acts detailed above, including the certifications made by Actelion and CVC, as well as the wire communications in furtherance of their Scheme, were in done willingly, and in furtherance of the purpose of the Scheme.

265. If the certifications by Actelion to CMS had not been made, Assignors would not have purchased Actelion's products. If CVC's certifications had not been made, CVC would not have been permitted to administer its PAH Fund and the Assignors and Class Members would not have paid for the claims resulting from the unlawful conduct. If the Scheme did not exist, pharmacies would have received substantially less co-pay revenues, and the pharmacies would not have submitted AKS-tainted claims to Assignors and Class Members. If the Scheme did not exist, Actelion would not have been able to continuously increase the prices of Actelion Drugs and still remain profitable to the extent that it was.

266. These predicate acts allowed the continuance of the Scheme to increase the quantity of the Actelion Drugs and maintain supra-competitive prices. As a result of the Scheme, Assignors and Class Members paid supra-competitive prices for Subject Actelion Drugs at artificially inflated volumes.

267. Defendants, including officers, directors, agents, and principals of both organizations, participated in all of the predicate acts. These individuals sent or caused to be sent false certifications through the mail and wire facilities. These individuals repeatedly, and

continuously, used the mail and wires in furtherance of the Scheme.

268. The intended and direct victims of the Scheme were Assignors and Class Members.

269. The violations of the Travel Act and Mail and Wire Fraud included transmission of false claims and the unlawful transmission of data and communications to further the racketeering Scheme over a period of at least five years involving harm to multiple parties.

270. CVC was involved in similar fraudulent schemes with other drug manufacturers. It was engaged in similar schemes with Jazz, United Therapeutics, and Lundbeck, each of which resulted in settlements with the United States for violations of the AKS and FCA in 2018. Specifically, Jazz settled for $57 million, United Therapeutics settled for $230 million, and Lundbeck settled for $52.6 million. CVC's multi-faceted fraud involved multiple victims and predicate acts and is the type of broad and persistent racketeering activity that RICO was intended to stop.

271. As CVC's successor, Adira is liable for CVC's conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

272. The Co-payment Circumvention Enterprise and the predicate acts proximately caused injury to Assignors' and Class Members' business and property by, among other ways, triggering the Assignors' and Class Members' duty to purchase the Actelion Drugs and by driving up the cost of the Actelion Drugs. Defendants' scheme rendered the claims for the Actelion Drugs unpayable and Assignors and Class Members would not have (and could not have) paid if Defendants had not concealed their Scheme.

273. Accordingly, Defendants' violations of 18 U.S.C. §1962(c) directly and proximately caused injuries and damages to Assignors and Class Members, entitling Plaintiffs to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

SECOND CLAIM FOR RELIEF
Violations of 18 U.S.C. § 1962(d) Through the Use of the Co-Payment Charity Scheme
Against All Defendants

274. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

275. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions.

276. Defendants violated § 1962(d) by conspiring to violate § 1962(c). The object of this conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Co-payment Circumvention Enterprise described previously through a pattern of racketeering activity.

277. Defendants knowingly agreed that Actelion would perform services that would facilitate the illicit activities of the Co-payment Scheme. Actelion steered the Actelion Drugs patients away from its manufacturer-sponsored free-drug fund and into CVC's PAH Fund. Actelion also provided CVC with "donations" so that CVC could pay the co-payments of Actelion's "customers" in CVC's funds. Actelion also sent certifications over the interstate mails and wires claiming it was in compliance with federal law, including the AKS and FCA. Actelion also used the data CVC sent it, in violation of the AKS and FCA, to determine how much money it was making from its "donations" to CVC and how much *more* money it could make by increasing its "donations."

278. Indeed, Actelion and CVC were not engaged in parallel conduct but were working together and had a meeting of the minds that they could both profit from the Co-payment Circumvention Enterprise. The shared data showed how much money Actelion made the prior year before from its "donations" to CVC and how much more it could make by increasing its "donations." It thus set out a roadmap of illegal activities and profits.

279. Further, Defendants knowingly agreed that CVC would perform services that would facilitate the activities of the Co-payment Circumvention Enterprise and those who were running it in an illegal manner. Some of the services that CVC performed were steering people into its funds,

and helping to enroll patients into Medicare and Medicaid Programs. Actelion would then pay CVC agreed-upon bribes for each patient CVC successfully enrolled in Medicare and Medicaid Programs for the Actelion Drugs.

280. CVC also sent certifications over the interstate mails and wires claiming it was in compliance with federal law, including the AKS and FCA. CVC also sent Actelion data, in violation of the AKS and FCA, so Actelion could see how much money it was making from its "donations" to CVC and how much *more* money it could make by increasing its "donations." Indeed, this sharing of data shows that Actelion and CVC were not engaged in parallel conduct but were working together and had a meeting of the minds that they could both profit from the Co-payment Scheme. CVC knew that the more money it accepted in "donations" from Actelion, the more money would go into the pockets of CVC's officers and directors. By illegally giving Actelion this data, CVC was soliciting greater contributions.

281. Further, Actelion and CVC knowingly agreed to perform services that would facilitate the activities of the Co-Payment Circumvention Enterprise and those who were running it in an illegal manner. Actelion steered people towards CVC's co-payment assistance funds by using CVC data to ensure Actelion could verify that its "donations" provided co-pays for the Actelion Drugs. Actelion and CVC caused false certifications to be sent over the interstate mail and wire facilities claiming they were in compliance with federal law, including the AKS and FCA. CVC sent Actelion data, in violation of the AKS and FCA, so that Actelion could see how much money it was making from its "donations" to CVC, and how much more money it could make by increasing its "donations." Indeed, this conduct shows that Defendants did not engage in parallel conduct but worked together and had a meeting of the minds that they could each profit from the Co-payment Scheme. Actelion knew that if it provided more "donations," CVC would provide more co-pay assistance, thereby increasing Actelion's profits. Thus, by illegally providing data to Actelion, CVC managed to increase its own profits—as well as Actelion's profits.

282. Defendants knowingly agreed that one or all of them would commit at least two instances of Travel Act violations or mail and wire fraud (or cause an innocent third-party to send false statements over the mails and wires). Defendants had actual or constructive knowledge that

CVC had certified to HHS that it would not share data with manufacturers, allow manufactures to exert influence over it, steer people to particular drugs, or serve as a conduit for drug manufacturers. In short, Defendants knew that CVC had certified that it would abide by the AKS and FCA. Defendants knew that the Scheme they were engaged in or were going to engage in was going to make all these certifications false. They also knew that each time a pharmacy filled a prescription for someone in CVC's funds, any certifications the pharmacist made that he or she would abide by federal law would be false. Actelion also knew that any certifications it made to HHS or the Government about its compliance with federal law would be false.

283. Defendants knew that any communications they had over the telephone, e-mail, or text message in furtherance of the Scheme would be predicate acts.

284. Defendants agreed to pursue the same objective of profiting illegally from the Co-payment Scheme. They agreed to divide the work of accomplishing this objective. Actelion would make the "donations"; CVC would provide data; and they would both steer clients and make false certifications. Defendants intended to further this endeavor, which, as described above, when completed, amounted to a violation of 18 U.S.C. § 1962(c) that proximately and directly caused injury to the Assignors and Class Members.

285. As CVC's successor, Adira is liable for CVC's conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

286. Plaintiffs bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

THIRD CLAIM FOR RELIEF
Violations of State Consumer Protection Laws
Against All Defendants

287. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

288. Defendants engaged in unfair, false, unconscionable, or deceptive acts or practices in violation of various state consumer protection laws, as set forth below.

289. Defendants directly misrepresented to Assignors and the Class Members that they were complying with federal and state laws, including laws against bribery, kickbacks, and false claims to the government.

290. Defendants utilized the Scheme to eliminate price sensitivity in order to raise prices for the Actelion Drugs to supra-competitive levels.

291. Defendants intended for payers such as Assignors and Class Members to rely on these certifications. The intention may be inferred by the very nature of the representation, whose sole purpose was to procure payment for the Actelion Drugs. These representations and certifications were made in an effort by Defendants to have the consuming public use the CVC fund and were addressed to the market generally by having improper and unnecessary prescriptions for the Actelion Drugs paid for by Medicare, Assignors, and the Class Members. The ultimate consequence of this conduct is a significant injury to the consuming public by, among other things, imposing additional costs on the taxpaying public for Medicare.

292. Assignors and the Class Members relied on these misrepresentations to their detriment, which were material to their decision to pay for the Actelion Drugs.

293. As CVC's successor, Adira is liable for CVC's conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

294. Assignors and the Class Members were directly and proximately injured by Defendants' conduct suffered an injury in fact, and suffered actual, ascertainable damages.

295. Assignors and the Class Members would not have reimbursed for nearly as much of the Actelion Drugs as they did, had Defendants refrained from engineering the false representations or otherwise disclosed its schemes. Likewise, Assignors and the Class Members would not have paid nearly as much for each prescription of the Actelion Drugs as they did, had Defendants not eliminated price sensitivity through the Co-payment Scheme.

296. Accordingly, Plaintiffs and the Class Members in each of the below jurisdictions, seek damages (including statutory damages where applicable), to be trebled or otherwise increased as permitted by a jurisdiction's consumer protection law, and cost of suit, including reasonable

attorneys' fees, to the extent permitted by the below state laws.

California Unfair Competition Law (Cal. Bus. Code §§ 17000, et seq.)

297. Defendants' conduct occurred in "trade" or "commerce" within the meaning of Cal. Bus. Code Article 2 §§ 17020-17031.

298. The California UCL provides that "Any person who engages, has engaged, or proposes to engage in unfair competition shall be liable for a civil penalty." Cal. Bus. Code §17206(a).

299. Defendants' conduct constitutes "unfair or deceptive" acts in violation of the California UCL.

300. Defendants' illegal conduct substantially affected California trade and consumers.

301. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs here.

302. Defendants' conduct alleged in this Complaint occurred throughout the United States, including the State of California.

303. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of California.

304. Plaintiffs are entitled to recover their actual damages.

305. Plaintiffs also seek punitive damages, attorney fees, and any other just and proper relief under the California UCL.

***Connecticut Unfair Trade Practices Act (Conn. Gen. Stat. §§ 42-110a* et seq.)**

306. Defendants' conduct occurred in "trade" or "commerce" within the meaning of Conn. Gen. Stat. § 42-110a(4) ("Connecticut UTPA").

307. The Connecticut UTPA provides that "no person shall engage in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. § 42-110b(a).

308. Defendants' conduct constitutes "unfair or deceptive" acts in violation of the

Connecticut UTPA.

309. Defendants' illegal conduct substantially affected Connecticut commerce and consumers.

310. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs herein.

311. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of Connecticut.

312. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Connecticut.

313. Simultaneously with the filing of this Complaint, Plaintiffs served a copy on the Attorney General and Commissioner of Consumer Protection pursuant to Conn. Gen. Stat. § 42-110g.

314. Plaintiffs are entitled to recover their actual damages, punitive damages, and attorneys' fees pursuant to Conn. Gen. Stat. § 42-110g.

***Florida Deceptive & Unfair Trade Practices Act (Fla. Stat. §§ 501.201* et seq.)**

315. Plaintiffs, Assignors, and the Class Members are "interested persons" and "consumers" within the meaning of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"). Fla. Stat. § 501.203(6)-(7).

316. Defendants are engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

317. FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce[.]" Fla. Sta. § 501.204(1).

318. Defendants' conduct constitutes "unconscionable acts or practices, and unfair or deceptive acts or practices" under FDUTPA.

319. Defendants knew or should have known that their conduct was in violation of

FDUTPA.

320. Defendants' illegal conduct substantially affected Florida commerce and consumers.

321. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased number and size of payments for the Actelion Drugs described herein.

322. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of Florida.

323. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Florida.

324. Plaintiffs seek to recover against each Defendant the amount of their actual damages, attorneys' fees, and costs pursuant to Fla. Stat. §§ 501.211(2) and 501.2105(1).

Illinois Consumer Fraud & Deceptive Business Practices Act (815 Ill. Comp. Stat. 505/1 et seq.)

325. Defendants' conduct occurred in "trade" or "commerce" within the meaning of the Illinois Consumer Fraud and Deceptive Business Practices Act ("Illinois CFDBPA"). 815 Ill. Comp. Stat 505/1(f).

326. Defendants are "persons" within the meaning of the Illinois CFDBPA. 815 Ill. Comp. Stat. 505/1(c).

327. Assignors and the Class Members are "consumers" within the meaning of the Illinois CFDBPA. 815 Ill. Comp. Stat. 505/1(e).

328. The Illinois CFDBPA provides that "Unfair methods of competition and unfair or deceptive acts or practices… are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby." 815 Ill. Comp. Stat. 505/2.

329. Defendants' conduct constitutes "unfair or deceptive" acts or practices in violation of the Illinois CFDBPA.

330. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of RICO Defendants' unfair and deceptive practices

and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs herein.

331. Defendants' conduct alleged in this Complaint occurred throughout the United States, including the State of Illinois.

332. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Illinois.

333. Simultaneously with the filing of this Complaint, Plaintiffs served a copy on the Illinois Attorney General pursuant to 815 Ill. Comp. Stat. 505/10(d).

334. Plaintiffs are entitled to recover three (3) times the amount of actual damages resulting from Defendants' violation together with costs and reasonable attorney's fees. 815 Ill. Comp. Stat. 505/2W.

***Massachusetts Regulation of Business Practice & Consumer Protection Act (Mass. Gen. Laws ch. 93A, §§ 1* et seq.)**

335. Assignors, the Class Members, and Defendants are "persons" within the meaning of the Massachusetts Regulation of Business Practice & Consumer Protection Act ("Massachusetts CPA"). Mass. Gen. Laws ch. 93A, § 1(a).

336. Defendants are engaged in "trade or commerce" within the meaning of Mass. Gen. Laws ch. 93A, § 1(b).

337. Defendants' conduct, and Plaintiffs' injury occurred primarily and substantially which the Commonwealth of Massachusetts.

338. The Massachusetts CPA makes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce unlawful. Mass. Gen. Laws ch. 93A, § 2(a).

339. Defendants' conduct constitutes "unfair or deceptive acts or practices" under Massachusetts CPA.

340. Defendants knew or should have known that their conduct was in violation of Massachusetts CPA.

341. Defendants' illegal conduct substantially affected Massachusetts commerce and

consumers.

342. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs described herein.

343. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of Massachusetts.

344. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Massachusetts.

345. Plaintiffs seek monetary relief against Defendants measured as the greater of (a) actual damages in an amount to be determined at trial and (b) statutory damages in the amount of $25 for each Plaintiff. Because Defendants' conduct was committed willfully and knowingly, Plaintiffs are entitled to recover up to three times actual damages, but no less than two times actual damages pursuant to Mass. Gen. Laws ch. 93A, §§ 9 and 11.

346. Plaintiffs also seek punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Massachusetts CPA.

***Michigan Consumer Protection Act (Mich. Comp. Laws §§ 445.901* et seq.)**

347. Defendants' conduct occurred in "trade" or "commerce" within the meaning of Michigan Consumer Protection Act ("Michigan CPA"). Mich. Comp. Laws § 445.902(g).

348. Defendants are "persons" within the meaning of Michigan CPA. Mich. Comp. Laws § 445.902(d).

349. The Michigan CPA provides that "Unfair, unconscionable, or deceptive methods, acts, or practices in conduct of trade or commerce are unlawful." Mich. Comp. Laws § 445.903(1).

350. Defendants' conduct constitutes "unfair, unconscionable, or deceptive" methods, acts, or practices under the Michigan CPA.

351. Defendants' conduct includes, *but is not limited to*, several categories defined in the Michigan Consumer Protection Act. *See* Mich. Comp. Laws § 445.903(1)(a), (c), (s), (u), (w), and (z).

352. Defendants' conduct substantially affected Michigan trade or commerce, and consumers.

353. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair, unconscionable, or deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs herein.

354. Defendants' conduct alleged in this Complaint occurred throughout the United States, including the State of Michigan.

355. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Michigan.

356. Plaintiffs are entitled to recover their actual damages and reasonable attorney fees pursuant to Mich. Comp. Laws § 445.911(2)-(3).

***New York General Business Law (N.Y. Gen. Bus. Law §§ 349* et seq.)**

357. The New York General Business Laws ("New York GBL") makes unlawful "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 349.

358. Defendants' conduct constitutes "deceptive acts" in violation of the New York GBL.

359. Defendants' conduct was consumer oriented.

360. Defendants' conduct eliminated price sensitivity and raised prices in the relevant markets for the Actelion Drugs, which necessarily impacted consumers at large.

361. Defendants' conduct was consumer oriented since it was necessarily directed at Plaintiffs, consumers and/or other similarly situated entities.

362. Defendants' illegal conduct substantially affected New York commerce and consumers.

363. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the

Actelion Drugs described herein.

364. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of New York.

365. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of New York.

366. As a result of the foregoing willful, knowing, and wrongful conduct of Defendants, Plaintiffs have been damaged in an amount to be proven at trial, and seek all just and proper remedies, including but not limited to actual damages or $50, whichever is greater, treble damages up to $1,000, punitive damages to the extent available under the law, reasonable attorneys' fees and costs, an order enjoining Defendants' deceptive and unfair conduct, and all other just and appropriate relief available pursuant to N.Y. Gen. Bus. Law § 349.

Ohio Consumer Protections Laws
(Ohio Rev. Code Ann. §§ 1345* et seq.*; §§ 4165* et seq.*)

367. Defendants, Assignors, and the Class Members are "persons" within the meaning of the Ohio Consumer Sales Practice Act Ohio Rev. Code Ann. §§ 1345.01 ("Ohio CSPA") and the Ohio Deceptive Trade Practices Act Ohio Rev. Code Ann. §§ 4165.01. ("Ohio DTPA").

368. Defendants are "suppliers" within the meaning of the Ohio CSPA. Ohio Rev. Code Ann. § 1345.01

369. Defendants engaged in trade or commerce within the meaning of the Ohio CSPA and Ohio DTPA.

370. The Ohio CSPA specifies "No supplier shall commit an unfair or deceptive act or practice." Ohio Rev. Code Ann. § 1345.02.

371. The Ohio DTPA declares it unlawful for any person to engage in a deceptive practice in the course of the person's business, vocation, or occupation. Ohio Rev. Code Ann. § 4165.02.

372. Defendants' conduct constituted "unfair, deceptive acts or practices" in violation of the Ohio CSPA and Ohio DTPA.

373. Defendants knew or should have known that their conduct was in violation of **both** the Ohio CSPA and Ohio DTPA.

374. Defendants' illegal conduct substantially affected Ohio commerce and consumers.

375. Assignors and the Class Members relied upon Defendants' material misrepresentations regarding the certifications, their compliance with federal and state laws, including laws against bribery, kickbacks, and false claims to the government.

376. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs described herein.

377. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of Ohio.

378. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Ohio.

379. Plaintiffs seek actual economic losses, punitive damages, attorney's fees, and any other just and proper relief available pursuant to the Ohio CSPA and Ohio DTPA.

Puerto Rico Regulation of Commerce (P.R. Laws Ann. tit. 10, §§ 251 et seq.; P.R. Laws Ann. Tit. 31, §§ 5141 et seq)

380. Assignors, the Class Members, and Defendants are "persons" within the meaning of P.R. Laws Ann. tit. 10, §§ 251 *et seq.*

381. Defendants engaged in trade or commerce within the meaning of P.R. Laws Ann. tit. 10, §§ 251 *et seq*.

382. The Puerto Rico Regulation of Commerce states "[u]nfair competition, and unfair or deceptive acts or practices in trade or commerce are hereby decaled unlawful." P.R. Laws Ann. tit. 10, §§ 251 et seq.

383. Defendants' conduct constituted "unfair competition, and unfair or deceptive acts or practices" in violation of P.R. Laws Ann. tit. 10, §§ 251 *et seq.*

384. Defendants knew or should have known that their conduct was in violation of the P.R. Laws Ann. tit. 10, §§ 251 *et seq*.

385. Under P.R. Law Ann tit. 31, § 5141, "a person who by an act or omission causes

damage to another through fault or negligence shall be obliged to repair the damage so done.

386. Defendants' unfair, unconscionable, deceptive practices or acts violated P.R. Law Ann tit. 31, §§ 5141 *et seq*.

387. In an effort to conceal the Scheme, Defendants regularly omitted information and/or made false or misleading statements causing third parties to submit false certifications for payment of claims otherwise prohibited by federal law.

388. Defendants utilized the Scheme to raise prices of the Subject Actelion Drugs to supra-competitive prices, as explained above.

389. Plaintiffs suffered harm by paying and/or reimbursing AKS tainted claims at supra-competitive prices.

390. Defendants' illegal conduct substantially affected Puerto Rico commerce and consumers.

391. Assignors and the Class Members relied on Defendants' material misrepresentations about their certifications of compliance with federal and state laws, including laws against bribery, kickbacks, and false claims to the government.

392. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs.

393. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in Puerto Rico.

394. Plaintiffs' analysis of its Assignors' data identified one or more purchases the Actelion Drugs in Puerto Rico.

395. Plaintiffs seek damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under P.R. Laws Ann. tit. 10, §§ 251 *et seq*; P.R. Laws Ann. tit. 31, §§5141 *et seq*.

Rhode Island Deceptive Trade Practices Act (6 R.I. Gen. Laws §§ 6-13.1 et seq.)

396. Assignors and Class members are "persons" as defined by the Rhode Island

Deceptive Trade Practices Act ("Rhode Island DTPA").

397. Defendants engaged in an unfair or deceptive act or practice with the intent to injure consumers through supra-competitive profits.

398. Defendants' conduct was unfair or deceptive within the conduct of commerce within the State of Rhode Island.

399. Defendants' conduct amounted to an unfair or deceptive act or practice committed by a supplier in connection with a consumer transaction.

400. Defendants' unlawful conduct substantially affected Rhode Island's trade and commerce.

401. Defendants' conduct was willful.

402. Defendants deliberately failed to disclose material facts to Assignors and Class Members concerning the Defendants' unlawful activities, including the unlawful bribes Actelion provided to CVC as part of the Co-Payment Circumvention Enterprise.

403. Defendants' deception, including their affirmative misrepresentations and/or omissions concerning the price of the Actelion Drugs, constitutes information necessary to Assignors and Class Members to the cost of the Actelion Drugs.

404. The Actelion Drugs were purchased primarily for personal, family or household purposes.

405. Plaintiffs seek damages, court costs, and attorneys' fees under R.I. §§ 6-13.1, *et seq*, and any other just and proper relief available under the Rhode Island DTPA.

***Wisconsin Deceptive Trade Practices Act (Wis. Stat. §§ 100.18* et seq.)**

406. Assignors and the Class Members are part of "the public" under the Wisconsin Deceptive Trade Practices Act ("Wisconsin DTPA"). Wis. Stat. § 100.18(1).

407. Assignors and the Class Members are "persons" under Wis. Stat. § 100.18(1).

408. Defendants are each a "person, firm, corporation or association" under Wis. Stat. § 100.18(1).

409. The Wisconsin DTPA makes unlawful any "representation or statement of fact, which is untrue, deceptive or misleading." Wis. Stat. § 100.18(1).

410. Defendants' conduct constitutes "representation[s] or statement[s] of fact which [were] untrue, deceptive or misleading" in violation of the Wisconsin DTPA.

411. Defendants knew or should have known that their conduct violated the Wisconsin DTPA.

412. Defendants' illegal conduct substantially affected Wisconsin commerce and consumers.

413. Assignors and the Class Members suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and omissions and misrepresentations, at a minimum, in the form of increased payments for the Actelion Drugs.

414. Defendants' conduct alleged in this Complaint occurred throughout the United States, including in the State of Wisconsin.

415. Plaintiffs' analysis of its Assignors' data identified one or more purchases of the Actelion Drugs in the State of Wisconsin.

416. No business relationship, contractual or otherwise, existed or exists between Assignors, the Class Members, and Defendants.

417. Plaintiffs seek damages, court costs, and attorneys' fees under Wis. Stat. §100.18(11)(b)(2), and any other just and proper relief available under the Wisconsin DTPA.

FOURTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law
Against Defendants

418. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as though set forth at length above.

419. Defendants have benefitted from artificially inflated profits on the sale of the Actelion Drugs resulting from the unlawful and inequitable acts alleged in this Complaint.

420. Defendants' financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for direct and indirect purchases of the Actelion Drugs by the Assignors

and Class Members.

421. The Assignors and Class Members afforded Defendants an economic benefit in the form of profits, and other forms of compensation from unlawful overcharges and monopoly profits to the economic detriment of the Assignors and Class Members.

422. Plaintiffs' analysis of its Assignors' data identified one or more purchases of Subject Actelion Drugs in each of these States and Territories:

a. Connecticut;

b. Florida;

c. Illinois;

d. Massachusetts;

e. Michigan;

f. New York;

d. Ohio;

g. Puerto Rico;

h. Rhode Island; and

i. Wisconsin.

423. Defendants' conduct directly resulted in the unjust enrichment of the Defendants through the sale of the Actelion Drugs in each of the States and Territory mentioned above.

424. It would be futile for the Assignors and Class Members to seek a remedy from any party with whom they have privity of contract with for its direct or indirect purchases of the Actelion Drugs.

425. It would be futile for the Assignors and Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which the Assignors and Class Members purchased the Actelion Drugs, as they are not liable and would not compensate the Assignors and Class Members for unlawful conduct caused by Defendants.

426. The economic benefit of overcharges and artificially inflated volumes of prescriptions derived by Defendants through charging supra-competitive and artificially inflated prices for the Actelion Drugs is a direct and proximate result of Defendants' unlawful conduct.

427. The economic benefits derived by Defendants rightfully belong to the Assignors and Class Members, as they paid anticompetitive and monopolistic prices beginning in at least January 1, 2014, and continuing through the present, and they will continue to do so until the effects of Defendants' illegal conduct cease.

428. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States for Defendants to be permitted to retain any of the overcharges for the Actelion Drugs derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged in this Complaint.

429. Defendants are aware of and appreciates the benefits bestowed upon it by the Assignors and the Class Members.

430. Defendants should be compelled to disgorge all unlawful or inequitable proceeds received in a common fund for Plaintiffs' benefit.

431. A constructive trust should be imposed on all unlawful or inequitable sums received by Defendants traceable to the Assignors and Class Members.

FIFTH CLAIM FOR RELIEF
Violations of the Florida Civil Remedies for Criminal Practices Act
(Fla. Stat. § 772.101 *et seq.*)
Against All Defendants

432. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

433. At all times, as set forth above, Defendants' actions were unlawful under Fla. Stat. § 772.103(3), as they were all "employed by, or associated with, any enterprise through a pattern of criminal activity."

434. Defendants violated Fla. Stat. § 772.101 *et seq.*, by participating in or conducting the

affairs of the Co-Payment Circumvention Enterprise (as described more fully above) through a pattern of racketeering activity.

435. Plaintiffs, Assignors, and the Class Members are "persons" as defined in Fla. Stat. § 1.01, injured in their business or property, through Defendants' racketeering violations.

Description of the Co-Payment Circumvention Enterprise

436. RICO Defendants are "persons" under Fla. Stat. § 1.01.

437. Actelion, CVC, and Adira, are members of and constitute an "association in-fact enterprise."

438. The Co-Payment Circumvention Enterprise is an association-in-fact of individuals and corporate entities under Fla. Stat. § 772.101, and consists of "persons" associated for a common purpose.

439. The purpose of the Co-Payment Circumvention Enterprise was to maximize Actelion's profits and CVC's executive compensation.

440. The Co-Payment Circumvention Enterprise had an ongoing organization with an ascertainable structure and functioned as a continuing unit with separate roles and responsibilities. Actelion is the source of the schemes alleged, including providing kickbacks to subsidize payments for Actelion Drugs whose co-payments were provided by CVC.

441. For CVC's part, CVC accepted Actelion's bribes or kickbacks and provided unlawful payments for the Actelion Drugs.

442. Actelion and CVC, individually and collectively, fulfilled their roles in the Co-Payment Circumvention Enterprise.

443. Actelion and CVC were distinct legal entities with distinct purposes. Actelion is the architect of the Co-Payment Circumvention Enterprise, with the sole purpose to make as much money off the Actelion Drugs as possible before generic competition entered the market. For CVC, it was to raise the amount of money in the funds to justify paying higher salaries to their executives.

444. The Co-Payment Circumvention Enterprise had an existence that was distinct from the pattern of racketeering in which Actelion and CVC engaged. Actelion and CVC conspired with each other to minimize and/or conceal the amount of information Assignors received about the

claims for payment of the Actelion Drugs, materially resulting in Assignors' reimbursement of the purchase price of the Actelion Drugs that they would not have otherwise paid for. *See* Fla. Stat. § 817.234 ("A person commits insurance fraud punishable as provided in subsection (11) if that person, with the intent to injure, defraud, or deceive any insurer: 1. Presents or causes to be presented any written or oral statement, as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider contract, knowing that such statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claims[.]").

445. At all relevant times, Defendants operated, controlled, and managed the Co-Payment Circumvention Enterprise, through a variety of actions. First, CVC falsely represented the level of control that Actelion had over CVC in the PAP to the OIG on numerous occasions. Second, Defendants failed to disclose a material fact about the existence of the kickbacks and/or bribes in violation of Fla. Stat. § 817.234, (i.e., causing pharmacies to submit false submissions of payments to the Assignors and the Class Members.).

446. Defendants' participation in the Co-Payment Circumvention Enterprise was necessary for the successful operation of the schemes. The members of the Co-Payment Circumvention Enterprise all served a common purpose, which was to increase the fund to an enormous size while knowing each payment was a kickback, while minimizing the amount of information the Assignors, Class Members, and allegedly innocent third-party pharmacies, knew about the program. These affirmative acts and strategic omissions were material to the Assignors' and Class Members' decision to issue payment for the Actelion Drugs. The Co-Payment Circumvention Enterprise's actions maximized the revenue and profitability of the Enterprises' members by knowingly causing payments for the Actelion Drugs.

447. Fla. Stat. § 772.102 provides that criminal activity is any activity chargeable by indictment or information by among other statutes Fla. Stat. § 817.234. Section 817.234 criminalizes situations where health care companies, such as the Assignors and Class Members, are provided incomplete or misleading information about any fact or thing material to a claim for payment. Actelion and CVC violated Fla. Stat. § 817.234 by providing incomplete or misleading

information material to the Assignors' and Class Members' decision to issue payment for the Actelion Drugs.

448. Defendants committed numerous acts of racketeering by providing incomplete or misleading information related to the Actelion Drugs. Actelion and CVC knew or had reason to know that they were providing incomplete or misleading information about these claims.

449. Defendants knew or had reason to know that they were not providing complete or non-misleading information under Fla. Stat. § 817.234. Despite knowledge of these facts, they induced the Assignors and Class Members to make payment for claims that they otherwise would not have paid. Instead, Defendants knowingly provided incomplete information to enrich their bottom line.

450. Based on these omissions, the Assignors and Class Members provided payments for the Actelion Drugs throughout the United States, including Florida, based on half-truths, inaccurate information, and deliberate omissions. Defendants' omissions were material to the payment of the Actelion Drugs that the Assignors and Class Members provided payment for. Had the Assignors and Class Members known of the Co-Payment Scheme, they would not have submitted payment for the Actelion Drugs.

451. The Assignors and Class Members were the primary and intended victims of Defendants' unlawful scheme. The Assignors paid for the Actelion Drugs throughout the United States, including Florida, based on Defendants' omissions of material information under pursuant under to Fla. Stat. § 817.234,.

452. As part of this Scheme, Defendants caused pharmacies to submit false certifications and misled the Assignors and Class Members into reimbursing prescriptions of the Actelion Drugs. Actelion, CVC, and Adira, conducted or participated, directly or indirectly, in the Co-Payment Circumvention Scheme through a pattern of unlawful activity.

453. As CVC's successor, Adira is liable for CVC's conduct and is also independently liable for the conduct Adira engaged in that was in furtherance of the concealment and execution of the Scheme.

454. By reason of and as a result of Defendants' conduct, the Assignors and Class

Members were injured in their business or property.

455. Defendants' violations have directly and proximately caused injuries and damages to Assignors, Plaintiffs, and the Class Members. The Assignors, Plaintiffs, and Class Members have a right to bring this action for these damages.

456. Under Fla. Stat. § 772.11, Plaintiffs, and the Class Members seek their reasonable attorneys' fees and costs associated with prosecution of this action.

SIXTH CLAIM FOR RELIEF
Violation of Va. Code Ann. § 55.1-400 *et seq.* (formerly § 55-80 *et seq.*)
Against CVC and *Adira*

457. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

458. As detailed above, during CVC's dissolution process, all (or nearly all) of CVC's unrestricted and unobligated assets were given, assigned, and/or transferred to Adira—including some transfers when Adira was still known as FPH—including millions of dollars in cash, an unknown amount of investment assets, and a long list of office equipment and other valuable personal property.

459. During the Co-Payment Scheme, Plaintiffs became bona fide creditors under Va. Code Ann. § 55.1-400 *et seq*. as victims of the Co-Payment Scheme.

460. All or nearly all of CVC's gifts, transfers, conveyances, and assignments to Adira and FPH are voided as a matter of law as voluntary and/or fraudulent conveyances pursuant to Va. Code Ann. § 55.1-400. The millions of dollars, investment assets, and set of personal property that CVC transferred to Adira and FPH was not upon consideration deemed valuable in law.

461. When CVC completed these transfers, CVC was in the process of completing its disillusionment. As CVC's transferred all of its remaining unrestricted and unobligated assets to Adira, this transfer had the effect of rendering CVC insolvent.

462. At the time that CVC transferred its assets to Adira, Adira intended to continue CVC's business by using its assets for its gain and to the detriment of Plaintiffs and the Class

Members.

463. The aforementioned transfers were made with an actual intent to hinder, delay and defraud Plaintiffs.

464. The aforementioned transfers were made in reckless disregard for the Plaintiffs' rights and were made to leave CVC insolvent without the ability to pay its liabilities as they came due.

465. If any consideration was received by Adira in exchange for the asset transfers, such consideration was a sham, nominal consideration, inadequate and far less than a reasonably equivalent value for such assets.

466. At the time the transfers were made, Adira knew or should have known that the consideration for the transfers was nonexistent, a sham, nominal consideration, inadequate, and/or far less than a reasonably equivalent value for such assets.

467. Adira's transfers were not made in good faith. Because Adira had the knowledge aforesaid, it is not a bona fide purchaser.

468. The transfers discussed are fraudulent transfers under Va. Code Ann. § 55.1-400.

469. Plaintiffs and Class Members request that this Honorable Court enter an Order under Va. Code Ann § 55.1-400 *et seq*. to void, as voluntary and/or fraudulent, the transfers set forth here and that it order CVC and Adira, jointly and severally, to immediately turnover such assets, and that it enter a money judgment for the value of such assets in an amount to be determined at trial of this action.

SEVENTH CLAIM FOR RELIEF
Successor Liability as to Adira

470. Plaintiffs re-allege and incorporate by reference paragraphs 1-237 of this Complaint as if fully set forth herein.

471. During CVC's wind-up in 2019, Greg Smiley was the controlling or de facto President of both CVC and Adira.

472. CVC and Adira were both co-payment assistance charities that operated out of Virginia, Adira and CVC shared board members, transferred data, monies, and office equipment—

all without any or adequate consideration, between the two charities while Smiley was acting as President of both charities and James Rock was chairman for both charities. Additionally, several CVC employees—including other senior management personal—began working for Adira at the same time as the transfers. For example, Lauren Ruiz was Director of Patient Services at CVC from November 2011, until joining Adira in April 2019 as a Programs Manager. Additionally, Bruce Packett, who served as a director at CVC for several years, including from 2017-2020, has now also served on Adira's Board of Directors since 2018.

473. CVC and Adira even used the same accounting firm, Meadows Urquhart Acree & Cook LLP, to file their respective 2019 990 forms.

474. Adira is the successor corporation of CVC because, through the substantial contacts between Adira and CVC alleged herein, Adira impliedly agreed to assume the liabilities of CVC; the transactions and/or transfers between Adira and CVC resulted in a de facto merger; Adira is a mere continuation of CVC; and the transactions and/or transfers were fraudulent.

475. As a successor, Adira is jointly and severally liable to Plaintiffs and the class members for CVC's involvement in the Co-Payment Scheme.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs and the Class Members demand judgment against RICO Defendants as follows:

1. Awarding Plaintiffs and the Class Members actual, consequential, compensatory, statutory, treble, punitive, and other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

2. Awarding Plaintiffs and the Class Members equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

3. Declaring the alleged acts to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above;

4. Determining that this action is a proper class action, designating Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as

Class Counsel;

5. Awarding Plaintiffs and the Class Members their reasonable costs and expenses, including attorneys' fees; and

6. Awarding such other legal or equitable relief as the Court deems just and proper.

JURY DEMAND

Plaintiffs and the Class Members demand a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38.

Dated: December 2, 2022

Respectfully Submitted,

/s/ Alex R. Straus

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APPENDIX

Plaintiff MSPRC's Assignment to Demonstrate Standing

1. Certain series of MSPRC executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn MSPRC through its LLC Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MSPRC alleges the below assignment to demonstrate standing.

2. On May 12, 2017**, SummaCare, Inc. ("SMCR")** irrevocably assigned to MSP Recovery, LLC all its rights to recover against any liable third party (including RICO Defendants) for payments made on behalf of its Enrollees ("SMCR Assignment"). Specifically, the SMCR Assignment states the following:

> [SMCR] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [SMCR]'s right, title, ownership and interests in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [SMCR] that [SMCR] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [SMCR] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims[.]"

3. On June 12, 2017, MSP Recovery, LLC irrevocably assigned all rights acquired under the SMCR Assignment to Series 16-11-509, a designated series of MSPRC ("Series 16-11-509 Assignment"):

> Assignor … irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [Assigned Claims] (and all proceeds and products thereof) as such terms are defined in the [SMCR Assignment.]

4. SummaCare, Inc. consented to, acknowledged, approved, and ratified the Series 16-11-509 Assignment, which is memorialized in a letter dated September 5, 2018.

5. Consideration was given between each party in executing the SMCR Assignment and the Series 16-11-509 Assignment.

Plaintiff MSPA's Assignment Demonstrating Standing

1. MSPA was irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' Enrollees and health plan members. These assignments authorize MSPA to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MSPA alleges the below assignment to demonstrate standing.

2. On December 16, 2014, **Interamerican Medical Center Group, LLC ("IMC")** irrevocably assigned to MSP Recovery, LLC all of its rights to recover against any liable third party (including the Defendants) for payments made on behalf of its Enrollees ("IMC Assignment"). Specifically, the IMC Assignment, states the following:

> By way of this Agreement, [IMC] appoints, directs, and, otherwise, irrevocably assigns all of [IMC's] rights as it pertains to the rights pursuant to any plan, State or Federal statute(s) whatsoever directly and/or indirectly for any of its members and/or plan participants, and/or rights pursuant to any agreement[.]

3. On February 20, 2015, MSP Recovery, LLC irrevocably assigned all rights acquired under the IMC Assignment to MSPA ("MSPA Assignment 3"):

> Assignor hereby irrevocably assigns, transfers, conveys, sets over, and delivers to Assignee or its assigns any and all of Assignor's right, title, ownership and interest in and all rights and entitlements, that Assignor has, may have had, or has asserted against third parties from or relating to the Claims [assigned pursuant to the IMC Assignment].

4. IMC consented to, acknowledged, approved, and ratified the MSPA Assignment 3.

5. Consideration was given between each party in executing the IMC Assignment and the MSPA Assignment.

Plaintiff Series 44's Assignment Demonstrating Standing

1. Certain series of Series 44 executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Series 44 through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Series 44 alleges the assignments below to demonstrate standing.

2. Effective April 28, 2016, **Health First Health Plans, Inc. ("HFAP")** irrevocably assigned to MSP Recovery, LLC all rights under the to recover against any liable third party

(including the Defendants) for payments made on behalf of its Enrollees ("HFAP Assignment"). The HFAP Assignment expressly provides in pertinent part:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".
>
> …
>
> The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. This assignment is irrevocable and absolute.

3. Effective June 12, 2017, MSP Recovery, LLC assigned all rights acquired under the HFAP Assignment to Series 16-05-456, a designated series of MSPRC ("Series 16-05-456 Assignment"). The Series 16-05-456 Assignment states:

> [T]he undersigned Assignor … irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the Claims and Assigned Claims, (and all proceeds and products thereof, including any related assigned assets and assigned documents) as such terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida corporation and Medicare Advantage Organization and party to contract number H1099 with The Centers for Medicare & Medicaid Services, as the "Client" and health plan assignor, and [MSP Recovery], a Florida limited liability company (the "Assignment"); irrespective of when the claims were vested in Client, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party pursuant to the Assignment from the Client, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto.

4. On October 22, 2020, Series 16-05-456 irrevocably assigned all the rights it acquired from MSP Recovery, LLC to Series 44-20-456, a designated series of Series 44 ("Series 44-20-456 Assignment"):

> Assignor . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-456] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to the [claims], as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreements.

5. Consideration was given between each in executing the HFAP Assignment, the Series 16-05-456 Assignment, and the Series 44-20-456 Assignment.

Plaintiff Claims PROV's Assignment Demonstrating Standing

1. Certain series of Claims PROV executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims PROV through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims PROV alleges the assignments below to demonstrate standing.

2. On May 24, 2021, **Centro de Pediatria y Medicina de Familia de Villalba, C.S.P.** ("CPMF") irrevocably assigned all its rights and claims to recovery against any liable entity (including the RICO Defendants) for payments made on behalf of its Enrollees pursuant to its Government Healthcare Program to Series 21-04-1561, a designated series of Plaintiff Series Prov ("CPMF Assignment"). Specifically, the CPMF Assignment, states the following:

> Assignor irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all of Assignor's Claims arising from and related to the Claims Data transferred, provided or sent to MSP Recovery, these Claims encompassing the "**Assigned Claims**."
>
> Such assignment of the Assigned Claims is irrevocable and absolute, and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.
>
> CPMF Assignment, at 1.1.1, 1.1.2.

3. Consideration was given between the parties in executing this assignment.

Plaintiff Claims CAID's Assignment Demonstrating Standing

1. Certain series of Claims CAID executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims CAID through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims CAID alleges the assignments below to demonstrate standing.

2. On February 3, 2021, **Sal Health Group. LLC d/b/a Salubris** ("Salubris") irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its Enrollees to Series 19-10-1128, a designated series of MSP Recovery Claims CAID, Series LLC ("Salubris Assignment"). Specifically, the Salubris Assignment, states the following:

> [Assignor] irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its designated series, successors and assigns, any and all of Assignor's right, title, ownership, and interest in and to all of Assignor's Claims and rights arising from and related to the claims data transferred to Assignee (or its affiliates or services providers, including MSP Recovery, LLC) for the period encompassing dates of services from June 1, 2014 and continuing up to, including and through June 30, 2020, these Claims encompassing the "Assigned Claims." The assignment of the Assigned Claims set forth herein is irrevocable and absolute and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.

3. Consideration was given between the parties in executing this assignment.